FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

Commission		
CX 347	3550	
CX 540	3441	
CX 543	3443	
CX 544	3445	
CX 550	3455	
CX 551	3461	
CX 554	3461	(in camera)
CX 558	3466	
CX 575	3434	
CX 576	3447	
CX 682	3428	
CX 695	3491	
CX 1040	3474	
CX 1047	3513	
CX 1659	3386	
Schering		
SPX 93	3339	
SPX 112	3452	
SPX 194	3307	
SPX 614	3438	
SPX 675	3284	
SPX 676	3313	
SPX 687	3386	
SPX 2039	3319	

Schering

SPX 2040	3328
SPX 2042	3333
SPX 2060	3339
SPX 2155	3307
SPX 2209 to 2231	3414

Upsher

None

*All exhibits referenced in Joint Exhibit 4 are admitted into evidence by reference (copy attached).

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Wednesday, February 13, 2002

9:30 a.m.

TRIAL VOLUME 15

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

KAREN G. BOKAT, Attorney
MELVIN H. ORLANS, Attorney
PAUL J. NOLAN, Attorney
SUZANNE MICHEL, Attorney
SETH C. SILBER, Attorney
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2912

ON BEHALF OF SCHERING-PLOUGH CORPORATION:

JOHN W. NIELDS, Attorney
LAURA S. SHORES, Attorney
MARC G. SCHILDKRAUT, Attorney
JOSEPH M. LAVELLE, Attorney
VIVIAN S. KUO, Attorney
Howrey, Simon, Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800

ON BEHALF OF UPSHER-SMITH LABORATORIES:

ROBERT D. PAUL, Attorney
J. MARK GIDLEY, Attorney
CHRISTOPHER M. CURRAN, Attorney
White & Case, LLP
601 Thirteenth Street, N.W.
Suite 600 South
Washington, D.C. 20005-3805
(202) 626-3610

ON BEHALF OF AMERICAN HOME PRODUCTS:

ANIKA SANDERS COOPER, Attorney
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5667

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Let's reconvene docket 9297.

Any matters to take up before we call the next witness?

MR. LAVELLE: Not from Schering, Your Honor.

MR. CURRAN: Not from Upsher, Your Honor.

MS. MICHEL: Your Honor, I would just like to let you know and let Mr. Lavelle know that I intend to request voir dire on this witness and to renew our motion to limit his testimony --

JUDGE CHAPPELL: Hang on. Somebody needs to turn off whatever that is.

Sorry, go ahead.

MS. MICHEL: And we would renew our motion to limit his testimony as I'll argue based on the voir dire at that time.

JUDGE CHAPPELL: So, you want to voir dire this witness before he testifies, after he's sworn?

MS. MICHEL: After Mr. Lavelle establishes his credentials, I'd like to take voir dire of this witness and test the reliability of his opinion and the issue of whether or not it satisfies Daubert.

JUDGE CHAPPELL: Okay, call your next witness.

MR. LAVELLE: Thank you, Your Honor. We call Charles Miller.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

CHARLES E. MILLER

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name, please.

THE WITNESS: My name is Charles E. Miller.

DIRECT EXAMINATION

BY MR. LAVELLE:

Q. Good morning, Mr. Miller.

A. Good morning.

Q. Mr. Miller, you're a lawyer. Is that correct?

A. Yes.

Q. Where do you practice law?

A. In New York City.

Q. And with what law firm, sir?

A. Pennie & Edmonds LLP.

Q. How long have you been at Pennie & Edmonds?

A. About 31 years.

Q. And are you a partner at Pennie & Edmonds?

A. Yes, I'm a senior partner.

Q. And for how long have you been a partner at Pennie & Edmonds?

A. For -- for about 14 years, since 1978.

Q. Does Pennie & Edmonds specialize in a particular area of law?

A. Yes. I would like to correct my previous statement. Since 1978, that's 24 years, I believe.

Q. You've been a partner for 24 years?

A. Yes, I'm sorry.

Q. Does Pennie & Edmonds have an area of law in which it specializes?

A. Pennie & Edmonds specializes in intellectual property law.

Q. And for how long has Pennie & Edmonds been specializing in intellectual property law?

A. Since its founding in 1883.

Q. Thank you, sir.

Do you personally have an area of law in which you concentrate your practice?

A. I normally concentrate my practice in the field of patent law.

Q. Is there a specialized Bar for members -- for people who practice patent law?

A. Yes, with respect to practicing before the U.S. Patent and Trademark Office in patent matters, there

is.

Q. Are you a member of the Bar of the United States Patent and Trademark Office?

A. Yes, since 1967.

Q. Thank you.

Does Pennie & Edmonds represent Schering-Plough in any matters?

A. No. In fact, Pennie & Edmonds has been and is adverse to Schering-Plough in several matters, and consequently, when I was asked to accept this assignment, it was necessary for me to obtain waivers from those clients of the firm that are adverse to Schering-Plough, and those waivers were obtained.

Q. Thank you.

Have you personally done any work for Schering prior to this case?

A. No.

Q. Where did you get your law degree, sir?

A. From New York University in 1970.

Q. Prior to that, did you get an undergraduate degree?

A. Yes, prior to my law school education, I was graduated from Columbia College in 1963 with a Bachelor's Degree in chemistry. After that, I received the Master's of Science degree in chemistry from

Columbia University. And after that, in 1966, I was graduated with a degree of Ph.D. in organic chemistry.

Q. What was the subject matter of your thesis in your Ph.D. pursuit, sir?

A. My Ph.D. thesis process was related to synthetic approaches to aureomycin, which is a type of antibiotic.

Q. Thank you.

Would you tell us what your practice consists of at Pennie & Edmonds?

A. My practice at Pennie & Edmonds consists to a large extent of litigation and counseling and consulting with clients with respect to opinion work and licensing matters, and I also manage a substantial docket of patent prosecution cases.

Q. Do you represent clients in litigation?

A. Yes.

Q. Do you represent clients in arbitration matters?

A. Yes, I have represented scores of clients in arbitration matters.

Q. Have you also acted as an arbiter from time to time?

A. Yes, particularly under the auspices of the American Arbitration Association, the International

Chamber of Commerce and the World Intellectual Property Organization.

Q. Thank you, sir.

Have you been appointed as a special master to take evidence by a federal district court judge?

A. Yes.

Q. Would you explain that matter to us, please, tell us a little bit about it?

A. In about 1988, I was appointed a special master by the U.S. District Court for the District of Massachusetts in a patent infringement litigation between 3M and Ampad Corporation in a case involving a series of U.S. patents relating to the adhesive material that is applied to sheets of paper that we are all familiar with, for example, they are sold under the trademark Post-It Notes.

Q. And what did you do as special master in that case?

A. My task as special master in that case was to -- primarily to conduct the evidentiary hearing, that is to say, the trial in the case, to receive evidence, make rulings on admissibility of evidence and to finally render a special master's report containing my findings of fact and conclusions of law, and this was all pursuant to what I believe is Rule 53 of the

Federal Rules of Civil Procedure.

Q. And did you, in fact, preside over a trial?

A. That was a trial that I presided over, yes.

Q. And how long did that trial last?

A. Several months.

Q. And did your report include findings of fact and conclusions of law?

A. Yes.

Q. Was your report accepted by the federal judge?

A. The report was reviewed by the parties, and the case was settled as a result of that report.

Q. Thank you, sir.

Sir, in your experience, are patent lawyers called on to evaluate the likely outcome of patent litigation?

A. This is part and parcel of much of the work that we do when we represent clients and particularly with regard to advising them in matters affecting their rights and potential liabilities in possible patent cases.

Q. Very good.

Are federal courts called on from time to time to assess the likely outcome of litigation?

A. I think it happens fairly often, particularly in the context of what we call preliminary injunction

motions, which are brought by plaintiff patent owners against -- are motions filed by plaintiff patent owners seeking to enjoin the defendant from continuing the accused activity pending the outcome of the case. The judge conducts a hearing in order to ascertain a number of factors that are required to be considered in deciding whether or not to issue a preliminary injunction.

One of those factors, and this gets to your question in particular, is the consideration of the evidence presented to the judge and a decision that he must make is whether -- whether the plaintiff would be likely to succeed on the merits based on the evidence presented at the preliminary injunction hearing.

Q. Thank you, sir.

On what matters does a patent lawyer rely in attempting to evaluate the likely outcome of litigation, patent litigation?

A. Well, certainly he would evaluate the -- and study and comprehend the patent itself. He must consider the prosecution record of the patent in the Patent and Trademark Office when it's pending as an application. He must consider the nature of the product that his client is concerned with, you know, in the context of whether or not there would be any

liability on the part of that client for patent infringement.

Q. Thank you.

Are there objective sources of law available for patent lawyers to consult in evaluating the outcome of the patent litigation?

A. I'm not sure I understand that question.

Q. Okay. Where do you turn to to understand the law you apply is all I'm really asking you.

A. Well, you determine first what are the likely issues to be decided in the case, the material issues, and then the attorney will have to assess the law that is applicable to that issue during the period in which the litigation would be pending.

Q. Have you been called on in your profession to evaluate the likely outcome of patent litigation?

A. Yes, many times.

Q. Are you a member of the Bar of the United States Supreme Court?

A. Yes, I am.

Q. Are you a member of the Bar of any United States courts of appeals?

A. Yes, the Court of Appeals for the Federal Circuit, which is the appellate court that handles most patent appeals; the Court of Appeals for the Second

Circuit; and the Court of Appeals for the Fourth Circuit.

Q. Are you a member of the Bars of any United States Federal District Courts?

A. Yes, I am a member of all of the district courts -- Federal District Courts in the state of New York, there are four of them, and a member of the Federal District Court for the District of Columbia.

Q. Are you a member of the United States Court of Federal Claims?

A. Yes, I am.

Q. Okay. Are you a member of the American Bar Association?

A. Yes.

Q. Are you a member of the American Intellectual Property Law Association?

A. Yes.

Q. Are you a member of the New York State Bar Association?

A. Yes, I'm a member of the New York State Bar Association, and in that context I'm an active member of the Federal Litigation Committee of the New York State Bar Association.

Q. Thank you.

Are you a member of the American Chemical

Society?

A. Yes.

Q. Sir, in your book, would you turn to Exhibit SPX 675. Do you recognize Exhibit 675?

Your Honor, I put a book on your -- on your stand as well.

JUDGE CHAPPELL: Thank you.

THE WITNESS: This is my resume or curriculum vitae which I provided to Mr. Lavelle at the outset of my assignment.

BY MR. LAVELLE:

Q. Is the CV correct and reasonably up to date?

A. It's essentially up to date, yes.

Q. And is it correct so far as what it sets forth?

A. I believe so, yes.

MR. LAVELLE: Your Honor, at this time I am going to offer Mr. Miller as an expert in patent law and the evaluation of patent litigation.

JUDGE CHAPPELL: Do we have an objection?

MS. MICHEL: I'd like to conduct voir dire on this witness, Your Honor, in order to better define the scope under which we would accept him as a -- his expertise.

JUDGE CHAPPELL: Did you tell me earlier you're renewing a motion in limine that you filed earlier?

MS. MICHEL: We do have a motion in limine pending regarding this witness.

JUDGE CHAPPELL: Okay. Do you have a copy of it, and does respondent have a copy of their opposition and response to that motion in limine?

MR. LAVELLE: Your Honor, I thought you had denied their motion in limine once already. I think they're going to renew something you already denied.

JUDGE CHAPPELL: Mr. Lavelle, I'm asking if you have a copy of it.

MR. LAVELLE: I'll look, Your Honor.

Your Honor, I have a copy of our opposition that I am happy to hand up to you if it would be helpful.

JUDGE CHAPPELL: Do you have one that's not marked up?

MR. LAVELLE: I have one that only has yellow highlighting.

JUDGE CHAPPELL: Since complaint counsel wants to take the witness on voir dire, I'm going to request that you provide me a copy of the motion in limine and any response that was filed to it, and I'll take a break until you can do so.

MS. MICHEL: Your Honor, I have a copy here.

JUDGE CHAPPELL: Do you have the response? I

need a clean copy.

MS. MICHEL: Let me see if I -- yes, I do.

JUDGE CHAPPELL: And I am going to give it back to you when I'm through.

MS. MICHEL: Yes, Your Honor.

JUDGE CHAPPELL: Now, let's just take a break while I refresh my recollection.

MS. MICHEL: Yes, Your Honor. There are only a limited number of pages in the motion that are pertinent to this witness.

JUDGE CHAPPELL: Thank you.

(Pause in the proceedings.)

JUDGE CHAPPELL: All right, Ms. Michel -- it is Michel?

MS. MICHEL: Michel, Your Honor.

JUDGE CHAPPELL: You may proceed.

VOIR DIRE EXAMINATION

BY MS. MICHEL:

Q. Good morning, Mr. Miller.

A. Good morning.

Q. Mr. Miller, you've never been qualified as an expert in antitrust law by any court, have you?

A. That's correct.

Q. And you're not an expert in antitrust law, correct?

A. Correct.
Q. You don't have any degrees in economics, do you?
A. No.
Q. You're not an expert in economics?
A. I am not.
Q. You've never been a district court judge?
A. No.
Q. Your thesis work in chemistry did not involve any polymer chemistry, did it?
A. No, it did not.
Q. You've never worked as a pharmacist in the field of pharmaceutical coatings?
A. I have not been a professional scientist.
Q. And you're not a person of skill in the art, then, in the area of pharmaceutical coatings.
A. I'm not an expert, but I consider myself knowledgeable.
Q. You're not a person of ordinary skill in the art in the field of pharmaceutical coatings, are you, Mr. Miller?
A. I really don't know. Probably not.
Q. Mr. Miller, did you hear Dr. Banker yesterday define a person of ordinary skill in the art for pharmaceutical coatings as a person with at least a

number of years of experience in that area?

A. I heard something to that effect, yes.

Q. And you're not a person with any experience in the field of pharmaceutical coatings, are you, Mr. Miller?

A. That's correct, I have not worked nor have I had any practical employment experience in the field of pharmaceuticals.

Q. You were paid by Schering for the time you spent forming your opinion and preparing your expert report in this case. Is that correct?

A. I expect to be paid, yes, irrespective of the outcome of this case.

Q. And you'll be paid by Schering for your time here today, correct?

A. Yes.

Q. Mr. Miller, you did not participate in the underlying patent litigation between ESI and Schering, did you?

A. No, I did not.

Q. You were not present at any of the hearings held before Judge DuBois.

A. I was not.

Q. And you were not present at any of the meetings in Judge DuBois' chambers.

A. Correct.

Q. You were not present at any of the meetings with the magistrate judge in the ESI case.

A. Correct.

Q. You didn't advise either ESI or Schering regarding the merits of the patent litigation while that case was pending.

A. That's correct.

Q. And your opinion regarding the merits of the litigation played no role in the parties reaching settlement then.

A. Could you repeat that question, please?

Q. Your opinion regarding the merits of the patent litigation played no role in the parties reaching settlement in that case.

A. No, my opinion followed it.

Q. You have not reviewed any documents contemporaneous to the patent litigation assessing the parties' chances of winning, have you?

A. No, I did not.

Q. You have not reviewed any attorney-client privileged documents from the patent litigation.

A. I have not.

Q. You don't know what the attorneys for Schering and ESI were telling each of their clients regarding

the odds of prevailing in the patent litigation at the time of settlement.

A. No, I don't.

Q. And so you will not -- you cannot offer any testimony on how either ESI or Schering viewed its chances of winning the patent litigation at the time of settlement.

A. No, I cannot. I have no information from either of those parties that would give me that information.

Q. Okay, thank you.

Now, ESI and Schering both had technical experts who testified at the Markman hearing, correct?

A. Yes.

Q. You've never discussed with Judge DuBois how he would have -- how he assessed the credibility of those experts.

A. No, I did not.

Q. You've never discussed the claim interpretation issues with Judge DuBois.

A. That's correct.

Q. You don't know how Judge DuBois would have ruled on the claim interpretation issues.

A. I do not know how he would have ruled for a fact. I don't know for a fact how he would have ruled

on that case.

Q. Thank you.

There was to be a trial following the Markman hearing. Is that correct?

A. Yes.

Q. You don't know what witnesses the parties would have called at the trial.

A. I have no specific recollection of any expert or any witness list having been provided to Judge DuBois at that time. I can -- I can surmise that some of the experts that -- whose reports I read would have been presented, but I don't know for sure, because I haven't -- as I said, I did not receive nor have I had any custody of any document indicating the specific witness list that would have been provided to the Court.

Q. So, you don't know how Judge DuBois would have assessed the credibility of any witnesses that might have appeared at trial.

A. That would have been an element that I did not have any information on.

Q. You don't know --

A. That would be for Judge -- that would be Judge DuBois' own mental impressions, of which I cannot speak to.

Q. You don't know what exhibits the parties would have submitted at trial.

A. Not specifically.

Q. And you don't know which of those exhibits would have been entered into evidence.

A. Not specifically, but I believe that's -- I do know some of the exhibits that probably -- most likely would have been proffered and admitted.

Q. You can know some of the exhibits that would have been proffered, but you don't know all of the exhibits.

A. They may have been all of the exhibits. I don't know.

Q. You can't know all of the exhibits that would have been offered at trial.

A. That's probably correct.

Q. And you can't know how the lawyers' opening and closing arguments would have gone at trial.

A. No, I don't know that.

Q. And you don't know how Judge DuBois would have ultimately decided the patent case.

A. I do not know what Judge DuBois himself would have decided. That was a matter for him to decide in his own mind, which I have no privy to.

Q. So, you don't intend to offer any opinion on

the likely outcome of the patent litigation based on any personal knowledge of Judge DuBois' views.

A. That's correct.

Q. Mr. Miller, you formed an opinion on the likely outcome of the patent litigation between ESI and Schering. Is that right?

A. Yes.

Q. And you intend to offer that opinion testimony today.

A. Yes.

Q. Now, your technique for determining the likely outcome of the patent litigation was to form your own opinion on the likely outcome from the point of view of a hypothetical judge. Is that correct?

A. Yes.

Q. To form that opinion, you read selected portions of the written record. Is that right?

A. I read every piece of paper that was provided to me by counsel for Schering that would have been -- likely would have been evidence before the Court in this case, both by ESI as well as Key. I'm using Key rather than Schering.

Q. I'll try to do so also, then.

A. Okay.

Q. Counsel for Schering did not provide you the

complete written record in the ESI-Schering case.

A. I'm sorry?

Q. Counsel for Schering, in asking you to form your opinion, did not provide you with the complete written record available from the ESI-Schering case. Is that right?

A. I don't know if they provided me with every piece of paper that would have been proffered, but they provided me with what I considered to be a comprehensive record that would have been sufficient for me to assess objectively how the case probably would have turned out.

Q. Mr. Miller, the likely outcome of the patent litigation between ESI and Schering depends on how Judge DuBois would have determined the case. Isn't that right?

A. State it again, please.

Q. The likely outcome of the patent litigation between ESI and Schering depends on how Judge DuBois would have determined the outcome of the case.

A. Not necessarily. The likely outcome of how the case would have turned out would be something that I could -- that I have sought to and I believe I have assessed based on my objective review of the record. What Judge DuBois would have decided is unknown to

anyone since the case was settled.

Q. I think we can agree on that point.

Then your technique for assessing the likely outcome of the litigation does not consider how judge DuBois would have assessed the credibility of any potential witnesses?

A. I did not seek to delve into the mind of Judge DuBois. I had no way of doing so.

Q. And your technique for predicting or for coming to an opinion on the likely outcome of the patent litigation did not take into consideration the skill of the litigating attorneys. Is that right?

A. Not specifically, but I know that both sides were capable attorneys.

Q. Now, no court has ever accepted this technique of predicting the likely outcome of patent litigation that settled, have they?

A. I'm not specifically aware of a case in which that happened.

Q. So, no court has ever accepted this technique of reading parts of the written record in order to predict the likely outcome of patent litigation that settled as a reliable test.

A. I can't answer that question. I just don't know.

Q. You're not aware of any court accepting this technique as reliable. Is that right?

A. I don't recall if there was any. I don't know.

Q. Now, we can never know if your opinion on the likely outcome of the patent litigation is correct, because the case will never be tried. Is that right?

A. We can never know with 100 percent certainty.

Q. So, your opinion on the likely outcome can never be tested.

A. In terms of what the actual outcome of the litigation had it gone to trial, you're correct.

Q. We don't know whether your technique for predicting the likely outcome of the patent litigation gives reproducible results.

A. I don't -- I don't necessarily agree with that. In my testimony on direct, I was asked have I ever myself assessed the likely outcomes of litigations, and while you are correct that there may be no court decision in which that was taken into account, I can tell you that part and parcel of what I do and what most patent lawyers do who represent clients is to advise them repeatedly in matters that affect the likely outcome of a controversy that may develop in connection with potential patent infringement.

Also, during the course of patent infringement

litigation, it's almost always the case that an attorney would be called upon by his client to assess independently and objectively the likely outcome of the case as it heads toward trial. That's a continuing chore that patent lawyers perform on behalf of their clients. So, the assignment that I carried out in this case is not one that to me would be unique in the patent profession.

Q. So, you've evaluated the likely outcome of patent litigation for clients?

A. Yes.

Q. And you've been wrong in your evaluation at times; courts have decided against you. Is that correct?

A. I'm trying to think of a case where I was wrong. I have to tell you that I have never -- well, I don't want to sound overly confident, but I cannot recall any instance where I advised a client on the likely outcome of a litigation that I was representing it on that was contrary to the opinion that I rendered.

Q. How many cases -- what percentage of cases that you've offered such advice on have actually gone to trial and been decided by district court judges?

A. I've been involved in about four to six cases that went to trial.

Q. So, your sample size is about four to six cases?

A. Cases that actually went to trial, yes.

Q. Now, Mr. Miller, you agree that no one can quantify the odds of one party winning a patent litigation because of the unpredictable nature of patent litigation?

A. I don't think patent litigation is unpredictable.

Q. You agree that even when a party thinks that its case is a slam-dunk, it might not get the desired result?

A. It's impossible to predict the likely outcome of any case with 100 percent certainty, so your use of the term "slam-dunk" is not a defined term in this examination of me, but I -- I'm not sure I can really answer that question.

Q. Rachel, could you help me with the ELMO, please?

Mr. Miller, I'd like to direct your attention to -- let's see, actually, I can give you a binder if that would be helpful.

A. I can read it off of the screen.

Q. All right, or if you would like the complete transcript, I can also supply you with a binder with

your complete deposition transcript.

I'd like to direct your attention to --

A. May I ask you what this is?

Q. Actually, why don't I get out the binders. That would probably be easier for everybody.

Your Honor, may I approach the Bench and the witness to hand binders?

JUDGE CHAPPELL: Yes, you may. Thank you.

BY MS. MICHEL:

Q. Mr. Miller, your deposition transcript can be found at I believe it's the second tab in the binder. I would direct your attention to page 96, and beginning at the top of page 96, you were asked:

"QUESTION: Why is it hard to predict how a jury would have resolved fact issues?

"ANSWER: In a general sense?

"QUESTION: In this case.

"ANSWER: Well, this case, like other cases, no party can ever expect perfect answers, perfect verdicts, perfect judgments, perfect justice. You can only get what you can -- hopefully will be a reasoned and just result but not necessarily perfect, and there's always, therefore, an element of predictability. You can go in -- you know, you can go in with a case that you think is a slam-dunk, and it

doesn't turn out to be that way."

Mr. Miller, do you still agree with that statement?

A. Essentially, yes. I would have used a different term than "slam-dunk," however, if I were giving this answer again. I think that's a term that I think I would rather have substituted with the term "100 percent chance of winning."

Q. Now, Mr. Miller, you mentioned in preliminary injunction motions, a judge sometimes determines the likelihood of success on the merits?

A. He must decide that in deciding the -- in deciding what the motion -- on whether or not a preliminary injunction is to be granted.

Q. Now, but when a judge makes that assessment of the likelihood of success on the merits, he takes -- he takes evidence on the question; he takes testimony from witnesses and other evidence offered by the parties. Isn't that correct?

A. That's correct.

Q. And Judge DuBois never took testimony from the parties and evidence at a trial in this patent case, did he?

A. There was no trial in this case.

MS. MICHEL: Your Honor, at this time, I'd like

to make a motion to limit Mr. Miller's testimony. My understanding is that Mr. Miller is going to testify on the likely outcome of this patent litigation.

Now, we would accept Mr. Miller as a patent expert for the purposes of summarizing the evidence that was presented and available to the parties in the patent litigation and to explain how that evidence was relevant in the context of the patent law framework.

We, however, would not accept Mr. Miller's or object -- we would object to Mr. Miller's offering any opinion on the likelihood of the outcome or the likely outcome of this litigation for two reasons.

The first reason is that that kind of testimony is attorney argument. It is not expert witness testimony to be offered from the witness stand. It's essentially closing argument in the Schering patent and ESI patent case. We would -- if Mr. Lavelle would like to offer that kind of closing argument, we would not object to that, but we do object to the idea of an attorney being on the witness stand making legal arguments for a client.

We also would object to the idea that Mr. Miller can offer some kind of assessment of the likely outcome of this patent case separate from the idea of advocacy legal arguments for his client simply because

such testimony cannot be reliable. Mr. Miller's admitted he has no information on how Judge DuBois would have decided this case, and, in fact, he's not even trying to offer that kind of testimony. He's simply giving his own views on who would have won this patent case. That's attorney argument, and it's not reliable.

It's not reliable because Mr. Miller doesn't have the right kind of information to actually address the point and also because patent litigation is unpredictable. There's no way -- Mr. Miller can't satisfy the Daubert criteria here. He can't -- this technique of reading a written record and then predicting the likely outcome of a patent case has never been tested as reliable. It can't be tested, because we can never know how this case would have turned out.

JUDGE CHAPPELL: Response?

MR. LAVELLE: Yes, Your Honor, thank you.

As you know, Your Honor, we are offering as evidence and have been these past couple days evidence related to the objective merit of the ESI case.

JUDGE CHAPPELL: You haven't been offering legal opinions in evidence.

MR. LAVELLE: There has been quite a bit of

testimony about legal issues already, and today, we propose to call Mr. Miller to give some legal opinions as a part of summarizing the evidence and the issues that were likely to resolve the ESI case. His technique is one that courts use every day, and the technique of reviewing a written record and determining the likelihood of outcome of the case is precisely what district courts do on submitted records, what courts of appeals do when they review records.

His methodology is simply one of gathering the facts and applying the applicable law. It is -- it is generally accepted for 200 years in this country, and it's what courts and judges and patent lawyers do. It is relevant testimony to this case, because we are offering it to show a comparison of the merits of the patent case to the split of the term in the ESI settlement.

JUDGE CHAPPELL: How do you test the reliability of the principles and methods of his opinion?

MR. LAVELLE: You test it by asking, as they did extensively in his deposition, if he has considered the appropriate facts and applied the law correctly.

JUDGE CHAPPELL: Okay. What opinions is he going to offer?

MR. LAVELLE: He is -- the ultimate opinions that --

JUDGE CHAPPELL: Not what opinion but opinions. How many opinions -- I just want categories. Give me categories of opinions that you're planning to offer with this witness.

MR. LAVELLE: Likely outcome of the infringement issue; likely outcome of the entire case; and how the likely outcome of the case compares to the split of the patent life in the ESI settlement.

JUDGE CHAPPELL: Okay, I've re-reviewed the complaint counsel's motion in limine and I've re-reviewed your response, and you didn't cite any authority, not one case, that says that any court accepts legal opinions, and whether you did or not, that's not important right now. I will not accept legal opinions from a witness. Legal opinions are not evidence at all.

As complaint counsel has already stated, I agree with her, that's a place to be made -- that's to be made in argument. I will not accept legal opinions from an expert witness. Any other opinions that you think are sufficient, I think they've agreed to not object to patent type opinions, but legal opinions are excluded.

MR. LAVELLE: Okay, thank you, Your Honor. We'll proceed.

MS. MICHEL: Your Honor, can I seek a point of clarification? I understand an opinion on the likely outcome of the patent litigation to be a legal opinion.

JUDGE CHAPPELL: To me, Ms. Michel, a legal opinion is as a matter of law somebody won or somebody lost or somebody would have lost. For what it's worth, which isn't much, when an attorney wants to tell me I looked at the file and I think somebody would have won, I'm going to allow that, and I'm going to give it the weight it deserves.

Any other clarification you need?

MS. MICHEL: I apologize, Your Honor, but I'm afraid so.

So, Mr. Miller is allowed to testify on who he believed would have won the patent litigation?

JUDGE CHAPPELL: I am going to allow him, if proper foundation is laid, to tell us who he thinks would have won, but I am going to give it the weight it deserves.

MS. MICHEL: I understand Schering to be making some distinctions between this question of who would have won and the likely outcome of the patent litigation. I --

JUDGE CHAPPELL: If it's a -- if it's a legal opinion on -- as a matter of law, one side would have won or the other, that's a legal opinion, I'm going to disregard that, and if you have any doubts, you're free to object during the testimony.

MS. MICHEL: Thank you, Your Honor.

JUDGE CHAPPELL: And you may take your copies of the motions back.

MS. MICHEL: Yes, Your Honor.

JUDGE CHAPPELL: You may proceed.

MR. LAVELLE: Your Honor, for the record, is Mr. Miller accepted as an expert subject to the qualifications you stated on the record?

MS. MICHEL: No -- well, could I hear the proffer restated, please?

MR. LAVELLE: I would just ask that Mr. Miller be qualified as an expert in patent law and the evaluation of patent litigation subject to the guidance and direction the Court has provided and limitations that the Court has provided.

JUDGE CHAPPELL: Yes, he's accepted with the limitations I've just gone over.

MS. MICHEL: Thank you.

JUDGE CHAPPELL: You may proceed.

MR. LAVELLE: Thank you, Your Honor.

DIRECT EXAMINATION (cont)

BY MR. LAVELLE:

Q. Mr. Miller, do you have Schering Exhibit SPX 194 in your book, please?

A. Yes.

Q. And would you tell us once again what that document is?

A. This is a certified copy of U.S. Patent 4,863,743, which was the patent that was in suit in the Key v. ESI litigation.

Q. Very good, sir.

How does a patent holder secure a patent?

A. By filing a patent application in the United States Patent and Trademark Office.

Q. And who issues the patent?

A. The U.S. Patent and Trademark Office, which is a branch of the U.S. Commerce Department.

Q. Very good.

Where does Congress get the authority to issue and grant patents?

A. It has a statutory authority to grant patents under the U.S. Constitution, and in particular, Article I, Section 8, Clause 8.

Q. I'd like to show you Schering Exhibit SPX 2155. Do you have 2155, sir?

A. Yes.

Q. What is this excerpt?

A. This is an excerpt of the portion of the Constitution that I just referred to, Article I, Section 8, and it's Clause 8.

Q. And it gave Congress the authority to create the patent system. Is that correct?

A. Yes. This clause is the enabling clause that authorizes Congress to legislate in the area of patents and trademark -- and copyrights, sorry.

Q. When did Congress first exercise its authority to create a patent system?

A. I believe the U.S. Patent System was established in or around 1790 through the establishment of the U.S. Patent Office.

Q. Who examined the first U.S. patent applications?

A. One of the first if not the first and sole patent examiner at the time was Thomas Jefferson. He was the Secretary of State at the time.

Q. And who signed the first patent that the United States issued?

A. Patents at that time were signed by the President of the United States, so the first patent that would have issued in the early 1790s would have

been signed by George Washington.

Q. Thank you.

Sir, go back to SPX 194, if you would, please.

Oh, by the way, how many patents has -- have been issued in the United States since President Washington signed the first one?

A. Well, the current numbering of patents takes us well over I believe it's 6000 -- 6 million, I'm sorry, I misspoke, 6 million patents. A number of patents were issued prior to 1835 I believe possibly on a different numbering system, but many of those patents are now lost.

Q. Would you go back to Schering Exhibit 194, please. A patent has two principal parts. Is that right?

A. Yes, it has a -- it has what is known as a specification, which comprises two main parts. One is the description of the invention, and the other part is the claims.

Q. Okay, and I think there's no dispute that in this case the specification are the number of paragraphs beginning with -- or columns beginning with column 1. Is that right?

A. Yes.

Q. And the claims begin in column 8?

A. Yes.

Q. And they're the numbered paragraphs 1 through 12, correct?

A. Yes.

Q. What is the function of the specification of a patent?

A. The function of the specification is to describe the invention in clear, concise and exact terms to enable one of ordinary skill -- of skill in the art to which the invention pertains to carry out the invention, and I'm quoting to some extent the specific statute in the patent laws that defines what the specification is in terms of a descriptive portion.

Q. Okay. And what is the function of the claims?

A. The claims are to define the invention in such clear and such -- the invention is defined in the claims in such a way that it particularly points out and distinctly defines the subject matter that the owner of the patent defines or considers to be the invention and is patented.

Q. What exclusive rights does a patent give to its owner?

A. The exclusive rights that the patent owner has under a U.S. patent is the exclusive right to make, to use, to vend -- that is to say, to sell or offer to

sell -- and to import the subject matter of the invention that is covered by the claim.

Q. Is the exclusive right of the patent defined by what's in the specification or what's in the claim?

A. By what is in the claims.

Q. Okay. And those examples that are in the '743 patent, do they limit or define the exclusive rights of the patent?

A. No, they do not.

Q. Claims do that?

A. Yes.

Q. Thank you.

How long will this '743 patent be in force, sir? When will it expire, in other words?

A. The patent will expire in September of 2006, which is 17 years from the issue date of this patent.

Q. Is filing an abbreviated new drug application an act of technical infringement in some cases?

A. Yes, it's considered to be an act of technical infringement as opposed to a tortious act of infringement of the type that I explained before. It is provided for in a separate portion of Section 271 of the patent statute.

Q. Okay. And under what circumstances is filing an ANDA an act of patent infringement?

A. When an ANDA is filed with the Food and Drug Administration seeking marketing approval for the drug in question prior to the expiration of the patent, then that sets up the fact pattern for an infringement action, and that is what the exclusive rights pertain to.

Q. Thank you, sir.

Before we talk about the litigation, let's talk for just a minute about how a patent holder goes about receiving the patent. How do you go about applying for a patent?

A. The inventor, usually through his attorney, a patent attorney, will submit to the U.S. Patent Office a patent application which contains several parts, the primary part of which is what we just discussed, which is the specification, including the claims, and in some cases a drawing is appropriate, which is not the case here, together with a fee and a declaration by the inventors concerning certain aspects of the making of the invention.

Q. And what does the United States Patent Office do with these applications?

A. The United States Patent Office, since the United States is, among all countries in the world, is what is called an examining country, will in the Patent

and Trademark Office assign the patent application to an examiner who will test the patent application against a number of criteria which the patent law sets forth in determining whether or not to grant the patent.

Q. Are these patent examiners technically trained individuals?

A. Yes.

Q. And typically what sort of expertise do the patent examiners have in the art that they work in?

A. Well, examiners are usually hired on the basis of their technical qualifications in a particular field, and I understand that the Patent Office has certain criteria that it looks to in this regard, and I would say generally a patent examiner will have, at the minimum, a Bachelor's Degree in engineering or in one of the physical sciences.

Q. Very good, sir.

I'd like to show you a Schering exhibit, SPX 676.

Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes.

MR. LAVELLE: Thank you, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Okay, Mr. Lavelle, you may

proceed.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Do you have Schering Exhibit 667 in front of you, Mr. Miller?

A. Yes.

Q. What is this document?

A. This is a copy of the application record of the prosecution proceedings in the U.S. Patent and Trademark Office that matured into the issuance of the '743 patent. We call it the file history or the prosecution history of the patent.

Q. Very good.

And what does the prosecution history or the file history of the '743 patent contain?

A. Well, it contains initially the application itself, which must include the specification and the set of initial claims, and then it goes on to include copies of exchanges of communications between the applicant's representative and the examiner during the course of the examination process of the application.

Q. Were you present yesterday in Court when Mr. Nolan put various excerpts from amendments and the like on the screen?

A. Yes.

Q. Are those amendments the type of documents that are contained in the file history?

A. Yes.

Q. Thank you, sir.

What do patent lawyers do with this file history?

A. Well, in terms of the patent lawyer for a third party who is going to assess the merits of the patent itself, he must examine the prosecution record, this document (indicating) in the case of the '743 patent.

Q. And why is that?

A. Why is that?

Q. Yeah. Why do you consult this in determining sort of what's important about this issue?

A. There's information contained or may be contained in a prosecution record that is relevant to issues of -- that may be relevant to issues of infringement or validity.

Q. If the patent holder believes his patent is infringed, what recourse does he have?

A. Basically his recourse is to an action -- a civil action in Federal District Court. There is a specific statutory provision for that, and I believe it is Section 281 of the patent statute.

Q. Okay. Is there any other way to enforce a

patent other than filing a lawsuit?

A. Not really.

Q. What does a patent holder have to prove to prove his case in patent infringement litigation?

A. There are two things that the patent owner, that is to say the party asserting the patent, must establish by way of proof; that is, the ownership of the patent be in itself, so that the party asserting the patent has standing to bring the action, and second, a patent owner must persuade the court that the patent has been infringed.

Q. Very good, thank you, sir.

What relief does -- is the patent holder normally entitled to if it wins the patent case at trial?

A. Normally, in cases of tortious infringement under Section 271-A, the patent owner, if he prevails in the litigation, will be entitled to damages and may, and in most cases will be, awarded an injunction against further infringement of the patent.

Q. Okay. And when the infringement is a technical infringement under Section 271-E of the patent statute --

A. Yes.

Q. -- what relief is the patent holder normally

entitled to?

A. If he prevails, then he is normally entitled to a judgment in which the approval of the ANDA will be withheld until the patent expires, so that in effect, the prevailing patent owner will be able to preclude or essentially enjoin the marketing of that product until the patent expires.

Q. What defenses can a defendant assert in patent litigation generally?

A. Generally that the patent, first and foremost, is not infringed if it's an infringement action, that the patent is invalid, that the patent perhaps is unenforceable for one or more reasons.

Q. And what burden does the law place on a defendant who wants to challenge the validity or enforceability of a patent?

A. The burden on the party challenging a patent in terms of its validity is a burden that rises to the level of clear and convincing evidence.

Q. Okay, thank you, sir.

Is it possible to assess the likely outcome of patent litigation?

A. Yes, I believe so.

Q. How precise can one be in assessing the likely outcome of patent litigation?

A. One cannot be 100 percent precise; however, one can be precise to a high degree of reliability depending upon the materials with which he has to work with.

Q. Well, first of all, why is 100 percent precision impossible?

A. Because there are elements of consideration that are not available, would not be available to someone before the trial. The -- the demeanor evidence exhibited by witnesses on the stand, the quality of the advocacy, the biases of the judge, these are elements that would prevent a 100 percent precision in assessing the outcome of a patent infringement litigation.

Q. And accepting that, would you explain why it is possible nonetheless to be fairly precise in your evaluation?

A. In my evaluation, I was presented with essentially the record that would have been presented to the court in determining the outcome of that case. This was a Bench trial; it was not a jury trial. It was to be a Bench trial, and attorneys who routinely advise clients on the basis of their assessment of the likely outcomes of litigation I believe are well equipped to objectively assess the likely outcome of a litigation, and I would point out that my assignment in

this case was to objectively assess how this case would have turned out had it gone to trial on the basis of what is essentially the record that would have been before the judge.

Q. Okay, let's talk about that a little bit. Could I have SPX 2039, please, if we can talk about this, please, let's just orient ourselves a little bit.

Okay, the ESI case was filed -- do you remember when it was filed, Mr. Miller?

A. It was filed I believe in early 1996.

Q. And as we've heard, it was pending before Judge DuBois?

A. In the Eastern District of Pennsylvania in Philadelphia, yes.

Q. And just for the record, would you identify which claims were at issue in the ESI litigation?

A. The claims that were at issue and that would have been the subject of the infringement case had it gone to trial were claims 1 and claims 5 through 8.

Q. Okay, thank you, sir.

And they are the numbered paragraphs 1 and 5 through 8 at the back of the '743 patent?

A. Yes.

Q. Is it adequate for or purposes today to just talk about claim 1?

A. Yes, claim 1 is a -- is the broadest claim in the patent. And certainly relative to the other claims, 5, 6, 7 and 8, yes, it would be typical and sufficient to focus our attention on claim 1.

Q. Okay. The ESI case was resolved in January of '98 after a claim construction hearing?

A. That's correct.

Q. Okay. And we've heard some testimony about that claim construction hearing yesterday, correct?

A. Yes.

Q. What relief was Schering seeking in the ESI case?

A. Well, as I mentioned before, Schering was seeking to exclude the marketing approval and consequently the marketing of the product that was the subject of ESI's ANDA, and that product I believe was called Micro-K tablets of potassium chloride.

Q. Very good.

What relief would Schering/Key have received if they won the patent case?

A. If Key had won the patent case, they would have -- they would have obtained a judgment pursuant to which the court would have ordered the -- either the post -- either the deferral of the approval of the ANDA until the expiry of the patent if the ANDA had not yet

received approval, or if it had received approval, then the court would have enjoined the carrying out of the marketing of that product until the expiration of the '743 patent.

Q. Very good.

You've told us what you were asked to do in this case. Would you tell us or summarize at least for us the materials that you reviewed in attempting to reach an objective assessment of the merits of this case?

A. What I reviewed -- and these were contained, I will say, in about six banker's boxes that were provided to me by Schering, you, sir, but a number of items beginning with the claims -- I'm sorry, the patent itself, the prosecution record of the patent, ESI's Paragraph IV certification which set the groundwork for the institution of the patent infringement litigation, the pleadings in the case in terms of the complaint and answer.

There were a number of interrogatories that were propounded in the case which I reviewed, and there were a number of motions, reports submitted in connection with those motions, exhibits associated with them, and a number of depositions taken during pretrial discovery.

Q. Did you read any hearing transcripts?
A. Yes.
Q. And did you review the or did you consider the transcript of the Markman hearing?
A. Yes.
Q. Thank you, sir.
Did you attend any of the depositions of technical witnesses in this FTC proceeding?
A. Yes.
Q. Did you undertake any independent legal research in connection with forming your opinion?
A. Yes.
Q. Would you explain that for us, please?
A. When I reviewed the materials that were provided to me and was able to focus on what I considered to be the issues triable in the case, most notably infringement, I conducted my own legal research on what the state of the law was during the period of the pendency of the action, and most particularly, what the state of the law would have been at the time the case would have been decided.
Q. Okay, thank you.
Did you reach an overall conclusion as to the likely outcome of the ESI case if it went to trial?
A. Yes.

Q. And what was your conclusion?

A. My conclusion, based on my objective assessment of both sides of the case, was that Key had a very strong case.

Q. Okay, thank you, sir.

Was there any issue that was the sort of overarching or dispositive issue in the ESI case based on your review?

A. The overarching or -- the most material issue in the case was that of infringement.

Q. Okay. Now, before we talk about infringement, were there other issues, in fact, in the case?

A. Yes.

Q. And would you explain first of all what other defenses ESI was asserting?

A. As I recall, ESI interposed defenses of patent invalidity, unenforceability on grounds of inequitable conduct. There may have been some other bases for their defenses. These are typically pleaded in in most patent cases. You must plead them if you're going to prove them, so it was not surprising that these were defenses that were interposed in the case.

Q. Did you evaluate the merit of ESI's defenses other than the infringement defense?

A. I looked at all the defenses that were pleaded

in the case by ESI, yes.

Q. Okay. And what did you -- what conclusion did you reach with respect to those other defenses?

A. The conclusion I reached was that these defenses would not have been material to the ultimate outcome of the case, that the overarching -- the issue would have been -- that was material to how the case would have been decided was the question of infringement.

Q. Sir, did Schering have a claim for damages in the ESI case?

A. Yes, there was a -- there was a claim for damages on the grounds or on the basis of ESI's -- well, one of its affiliate's production of an intermediate material in the United States, which was then allegedly shipped to a foreign country, and I believe it was Egypt, for assembly into the final product, perhaps the tablets themselves, and subsequent shipment and sale elsewhere outside the United States.

I have to say that this case was not one that I thought Schering had a very or Key had a very good position in. I saw very little, if anything, in the way of the necessary proofs of damages that they would have had to adduce, you know, at the threshold of the trial. So, I didn't think that was a position that Key

had a very strong case.

Q. Did you think that Key was likely to succeed on its damages claim?

A. I don't think so, because if the evidence that I saw would have been presented to the court, that there was issues not only as to where are the damages shown, I didn't see any evidence of that, and secondly, there was an issue as to whether the microcapsules -- the intermediate product that ESI was producing -- and this was an issue in the case, I can't speak to whether or not it was the fact -- whether or not the amount of the ethylcellulose -- and I will use the word EC as an acronym to simplify the pronunciation -- was there in sufficient quantity to come within the scope of the claim. That was an issue in the case, I believe.

Q. Let's then put that damages claim aside and turn to what you identified as the overarching issue, okay?

A. All right.

Q. And that was the infringement issue?

A. Yes.

Q. Okay. What is the first step in resolving the infringement issue in the ESI case?

A. The first step in resolving the infringement issue in the ESI case, as in any case, was the -- would

have been the construction of the claims, and most notably, as we just discussed a few minutes ago, claim 1 of the patent.

Q. Okay. And whose job was it to construe the claim?

A. Claim construction is a matter of or an issue of law that must be decided by the court.

Q. Okay. And we heard testimony yesterday and saw excerpts from something called a Markman hearing.

A. Yes.

Q. Do you recall that?

A. Yes.

Q. Would you explain what a Markman hearing is?

A. A Markman hearing, first of all, is named after a case, Markman vs. Westview Instruments, a case decided by -- it was either the Federal Circuit or the U.S. Supreme Court, I don't remember at the moment, but it was decided in the mid-1990s where the Court held that the construction of a claim must be the initial inquiry that a court makes in determining the infringement issue, and that construction must be done by the court, and it cannot be addressed by the jury.

There was no jury in this case, but in many patent trials there are juries, and in years past there was some debate as to whether the jury as a matter of

fact or the court as an issue of law should interpret the claim.

The law, as it was during the period of this litigation, had been settled by the Markman case. It is the court that must construe the claims, and a Markman hearing is the kind of proceeding that is conducted by the court to receive evidence and argument in that regard.

Q. Okay. And was -- there was a Markman hearing in the ESI case, right?

A. Yes.

Q. Okay. And what type of evidence -- what issue -- as to what issue -- strike that, let me start over.

As to what issue was evidence and argument received in the Markman hearing?

A. In general or specifically?

Q. In general.

A. Well, there was evidence as to the question as to does the -- what does the claim mean in terms of the recitations in that claim. Throughout the Markman hearing, the focus of attention was on the meaning of the claim in the context of a term that appeared in claim 1, which was the term "coating material."

Q. Very good.

Would you turn to Schering Exhibit SPX 2040, please. Do you recognize this claim chart, Mr. Miller?

A. This is a claim chart, yes.

Q. Okay. And on the left side of this claim chart is the patent. Is that right?

A. The left-hand column is a series of paragraphs which are taken from claim 1. Claim 1 itself reads as a run-on paragraph, and to facilitate a comprehension of what the claim covers, it is common to separate the claim into its component elements.

Q. Okay. And of all of those elements listed under claim 1, would you explain which ones the court had to construe at the Markman hearing in this case?

A. Well, the court has to construe all of the elements of the claim in order to properly construe the claim. As I said, though, the focus of the hearing devolved upon the meaning of the term "coating material," because that was the contentious issue with the -- the main contentious if not the primary contentious issue on the issue of infringement.

Q. Was there at the Markman hearing a dispute about any part of this claim other than the words "a coating material"?

A. I don't believe so.

Q. Okay. And just if we could briefly review, the

first box that begins, "A pharmaceutical dosage unit in tablet form," do you see that?

A. Yes.

Q. Do patent lawyers have a name for that part of the claim?

A. That's called the preamble.

Q. Okay. Was there any dispute between the parties as to what the terms in preamble meant?

A. No, there was not.

Q. And was there any dispute that ESI's product complied with the preamble?

A. There was no dispute in that regard.

Q. Okay. The first element of the claim in the next box, "a plurality of coated potassium chloride crystals," and it goes on, do you see where I am?

A. Yes.

Q. Was there any dispute between the parties as to the meaning of any word in that element?

A. No.

Q. Was there any dispute between the parties that that element was present in the ESI product?

A. No.

Q. Okay, going down to the next box, the "coating material" box?

A. Yes.

Q. Was there any dispute about any word in that element other than the three words, "a coating material"?

A. No.

Q. And was there any dispute that ESI's product contained ethylcellulose in the amount required by the claim?

A. No, there was no dispute on that amount.

Q. Going down to the next box, the HPC or the PEG?

A. Yes.

Q. Was there any dispute between the parties about any term in that claim element?

A. With regard to the word "hydroxypropylcellulose"?

Q. With regard to any portion of that claim element, "at least one member selected from the group," was there any dispute about any of the words in that element?

A. There was no dispute on any of those terms in the context of the Markman hearing.

Q. And was there any dispute that ESI's product contained HPC in the amount the claim requires?

A. No, there was no dispute in that regard.

Q. Okay. And the final element is, "said ethylcellulose has a viscosity greater than 40 cp."

Was there any dispute about any of those words?

A. No, there was not.

Q. And was there any dispute that ESI's product met that claim limitation?

A. No dispute.

Q. So, what the court had to do was figure out what the words "a coating material" mean?

A. That's where the focus of the court's attention ended up.

Q. In the Markman hearing?

A. In the Markman hearing, yes, sir.

Q. Would you explain to us the rules that you go through in understanding what a claim term means?

A. The rule on claim interpretation with respect -- and particularly with respect to what a particular term means is that you must consider the claim in its plain meaning, and therefore, what is the plain meaning of the term "a coating material" in the claim. If the meaning is plain and clear on its face, and if it's a technical term, it would be proper for the court to refer to technical dictionaries for a definition of the term, and if that is plain, the meaning is plain, then you do not need to go any further unless there is something in the specification of the patent -- that is to say, the descriptive

portion of the specification -- or something that was made of record during the prosecution of the patent application that would be found in the prosecution history of the patent that would contradict that plain meaning of the claim, and those three sources of information, the claim itself, the descriptive portion of the specification and the prosecution history, are what are called the intrinsic evidences of what the claim means.

Q. Thank you, sir.

Are claims limited to the examples in the specification?

A. No.

Q. Okay. We heard testimony about some of the examples in the '743 patent that show a coating mixture.

A. Yes.

Q. Do those examples limit the scope of claim 1?

A. No, they do not.

Q. Okay. And why not?

A. Because that is not the function of an example in a descriptive portion of a patent specification. The -- as I said before, the specification requires that the inventor describe the invention in a way that enables someone to carry out the invention but not

necessarily the only way of carrying out the invention. And also, it is a way of fulfilling the requirement that the inventor inform the public through the patent grant that he was in possession of an invention within the scope of the claims at the time that he filed his application.

Q. Thank you.

Does the inventor have to disclose every single possible, conceivable way of practicing his invention to get a patent?

A. He's not required by law, because it is generally impossible for an inventor to do so.

Q. Can the claims sometimes be broader than the examples in the specification?

A. Yes.

Q. Would you tell us a little bit about what relevance technical dictionaries have in claim construction?

A. Well, when looking at a -- the language of the claim itself in order to ascertain whether or not its meaning is plain and clear on its face, resort to technical dictionaries for the source of the definition of a technical term is proper for a court to do.

Q. Would you turn to SPX 2042 for a moment, please. This is that Dictionary of Pharmacy that we

looked at with the technical experts. Do you recall that?

A. Yes.

Q. Would you explain how a court is supposed to consult a technical dictionary or what use a technical dictionary is put to in connection with interpreting the claims?

A. Well, the term "coating material" in this context is clearly a -- is certainly a technical term, and referral or reference to technical dictionaries published at the time, as this one was, serves that purpose.

Q. All right. Sir, did you reach a conclusion as to how a properly instructed court would have construed the term "a coating material" in the ESI case?

MS. MICHEL: Objection, Your Honor. I think that calls for speculation on what a court would have determined. I think based on our earlier discussion, Mr. Miller can give his own view of how he thinks this claim should be determined, but he would only be speculating to conclude on what a court would have determined.

JUDGE CHAPPELL: You mean based on my earlier ruling?

MS. MICHEL: That, Your Honor, and also I

believe the question calls for speculation.

JUDGE CHAPPELL: Sustained.

BY MR. LAVELLE:

Q. Did you reach a view of your own about how the word "coating material" should properly be construed?

A. Yes.

Q. Would you explain that construction to us, please.

A. I came to the conclusion that the term "coating material" in claim 1 of the '743 patent covered the components of the coating material -- namely, HPC and EC -- either in one or more layers.

Q. And would you explain how you reached that conclusion?

A. Well, the -- I interpreted the -- I understood, based on assessing the submissions by both sides in this case and particularly from this dictionary definition and plain reading of the claim, that there was nothing in the patent specification description, nor in the prosecution record, that would suggest a narrow interpretation of the term "coating material." To me, "a coating material" is a term that we call generic to one or more variants of what a coating can be.

"Generic" is a term that patent lawyers use to

distinguish the specific. There are specific coatings. A coating can be a mixture of the components or it can be the components in one or more layers. There is no recitation in the claim itself that would lead me to conclude that one must construe this claim in terms of what the coating material is other than to be one or more layers of the materials that comprise the coating.

Q. If the term "coating material" is construed as covering a coating with one or more layers, what is the outcome of the infringement issue in the ESI case?

MS. MICHEL: Your Honor, again, I think the question is somewhat unclear in the issue of whether or not it's calling for Mr. Miller's personal opinion or whether it's calling for the outcome of that particular litigation, and I would object for that reason.

JUDGE CHAPPELL: It calls for a legal opinion. Objection sustained.

BY MR. LAVELLE:

Q. If the term "coating material" is construed to cover one or more layers --

A. Right.

Q. -- do you have an opinion as to whether or not all of the elements of claim 1 of the patent are present in ESI's product?

A. Yes.

Q. And what is your opinion?

A. My opinion is that all of the elements of the ESI product would satisfy the claim language of claim 1, including the word "coating material."

Q. Okay. And what -- if "coating material" were construed to cover one or more layers, what is your opinion on the likely outcome of the infringement case in the ESI litigation?

A. Based on my --

JUDGE CHAPPELL: Hold it, you're instructed not to answer that. I'm not allowing that, Mr. Lavelle.

MR. LAVELLE: All right, I apologize, Your Honor.

JUDGE CHAPPELL: That's a legal opinion dressed up in other clothes. I'm not allowing it. Move along.

MR. LAVELLE: Thank you, Your Honor. I apologize. I thought you were going to allow it and give it whatever weight it was accorded. That's the only reason I went there, Your Honor. I'll move on.

BY MR. LAVELLE:

Q. Did you attempt -- let me ask you then to consider the hypothetical where claim 1 is construed to require a mixture.

A. All right.

Q. Do you understand that?

A. Yes.

Q. Did you attempt to assess what -- and review the evidence as to whether or not there was, in fact, mixing in the ESI case?

A. Yes, I did.

MS. MICHEL: Your Honor, I'll object to any line of questioning asking Mr. Miller to give his opinion on whether or not there was any mixing. He's been qualified as an expert in patent law and not qualified as a technical expert on issues of pharmaceutical coating materials. It would be outside his scope of expertise to give an opinion on this issue.

JUDGE CHAPPELL: Sustained.

BY MR. LAVELLE:

Q. Did you attempt -- are you familiar with the dispute that was raised --

Your Honor, could I have a minute, please?

JUDGE CHAPPELL: Yes.

(Counsel conferring.)

BY MR. LAVELLE:

Q. While you were here in Court, did you hear Dr. Langer and Dr. Banker testify as to their opinions about whether or not the coating material in the ESI product were, in fact, mixed?

A. Yes.

Q. And you heard them testify that in their opinion, the coating material was, in fact, mixed?

A. The coating material in the ESI --

Q. ESI product.

A. -- product, yes.

Q. If Dr. Langer and Dr. Banker's opinions that there is, in fact, mixing is accepted as correct --

A. Yes.

Q. -- what was the likely outcome of the infringement issue in the ESI case?

MS. MICHEL: Objection, Your Honor, calls for speculation and also a legal conclusion.

JUDGE CHAPPELL: This witness is not going to give this Court an opinion on the likely outcome, Mr. Lavelle. Is that clear?

MR. LAVELLE: It is, Your Honor.

JUDGE CHAPPELL: Proceed. Sustained.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Sir, let me show you Schering Exhibit SPX 2060, please.

A. Yes.

Q. I'm sorry, that's not what I want to show you.

Would you turn to SPX 93, please.

A. Yes.
Q. Do you recognize this document, sir?
A. Yes.
Q. And what is that?
A. This is a copy of the settlement agreement between Key and Upsher that was entered into -- I believe it was during the month of June 1998.
Q. Did you attempt to determine when that settlement agreement permitted ESI to get a license to practice the patent?
MR. CURRAN: May I ask for the prior answer to be read back, please?
(The record was read as follows:)
"ANSWER: This is a copy of the settlement agreement between Key and Upsher that was entered into -- I believe it was during the month of June 1998."
BY MR. LAVELLE:
Q. Would you take a look at that and just review who the parties are to that agreement, please.
A. The parties to the agreement are Key Pharmaceuticals, the plaintiff in the action, and ESI Lederle or ESI.
Q. When you said Upsher, did you just misspeak?
A. Did I say Upsher? I'm sorry, I misspoke.

Q. This is a settlement agreement between --

A. Key and ESI in settlement of the ESI litigation that we have been discussing.

Q. And when does this agreement grant a license to ESI to practice the patent?

A. It's granted a license to ESI to introduce its generic version of the KCl tablets, I believe it was in January of 2004.

Q. Okay. And now could we go to 2060, please.

A. Yes.

Q. What does Exhibit 2060 depict, sir?

A. This is a time line depicting the events or depicting the -- actually the split of the remaining life of the '743 patent from January 1998, which was the month when an agreement in principle was arrived at between Key and ESI, and the expiry of the patent in September of 2006, and it shows that in January of 2004, ESI would be permitted to enter the market with its Micro-K 20 product under the settlement agreement.

Q. And how much sooner does ESI get on the market under this settlement agreement than if the patent were found valid and infringed?

A. Approximately 30 to 32 months.

Q. Did you attempt to compare the split of the patent life in the ESI license agreement to the likely

outcome of the litigation?

A. Yes, I did.

Q. Okay. And would you tell us how -- would you tell us, sir, if you reached a conclusion as to how the split of the patent life compares to the likely outcome of the litigation?

MS. MICHEL: Objection, Your Honor. For Mr. Miller to render an opinion on that issue would be effectively for him to be giving an opinion on the likely outcome of the patent litigation. For him to say something along the lines of that there was a 75 percent chance of Schering winning, therefore this 75 percent yellow bar was appropriate is effectively saying -- giving an opinion on the likely outcome.

JUDGE CHAPPELL: Response?

MR. LAVELLE: Your Honor, what the witness is going to testify to is the ultimate question of whether or not the split of the patent life fairly reflects or is more favorable to consumers than would be the likely outcome of the litigation. That's what I'm going to ask him.

MS. MICHEL: Two further objections in that case, Your Honor. First, I believe that opinion would call for speculation on the likely outcome of the actual ESI litigation rather than any opinion of Mr.

Miller.

A second point, Your Honor, to the extent that Mr. Miller connects that opinion to the benefit to consumers, he's now outside the scope of his expertise. He's effectively giving an opinion on the -- whether or not the agreement is a benefit to consumers. He has no expertise in economics or antitrust law.

MR. LAVELLE: Let me pose the question in a way that I think will cure the objection, Your Honor.

JUDGE CHAPPELL: So, you're withdrawing your question?

MR. LAVELLE: I will withdraw my question and attempt to pose one that I think is -- cures that concern.

JUDGE CHAPPELL: Then you're withdrawing the objection?

MS. MICHEL: I'll withdraw the objection because he's withdrawn the question and see the next question.

JUDGE CHAPPELL: Thank you.

BY MR. LAVELLE:

Q. Did you form your own opinion as to the likely outcome of the patent litigation?

A. Yes.

Q. And what was your personal opinion, based upon

your analysis, of the likely outcome of the patent litigation?

MS. MICHEL: Objection, calls for a legal conclusion.

JUDGE CHAPPELL: Sustained.

BY MR. LAVELLE:

Q. Well, then, let me ask my last question.

Would you compare for us, sir, the split of the patent life in the ESI settlement to your view of the likely outcome of the merits of the ESI litigation?

MS. MICHEL: Objection, Your Honor. He cannot make that comparison without making an implicit -- giving an implicit opinion on the likely outcome of the litigation.

JUDGE CHAPPELL: I agree. When you're asking what the likely outcome, all you're doing is saying who would have won, and that's a legal conclusion, and this is entangled in a legal opinion. So, I'm sustaining the objection.

MR. LAVELLE: I understand your ruling, Your Honor.

(Counsel conferring.)

JUDGE CHAPPELL: Yes, you may confer with counsel, Mr. Lavelle.

MR. LAVELLE: Thank you, Your Honor.

Your Honor, I want to ask -- I want to try one more line just to make sure that I understand and I'm complying with your instructions.

BY MR. LAVELLE:

Q. You heard the opinions expressed by Dr. Banker and Dr. Langer on the mixing question, correct?

A. Yes.

Q. In your opinion, what conclusion on infringement flows from the finding that there was mixing?

MS. MICHEL: Objection, Your Honor. That calls for a legal conclusion in the sense that whether or not a product with a mixed layer would infringe the claim calls for a legal conclusion on exactly what the claim meant, the claim interpretation, and that was the subject of the Markman hearing.

In other words, Your Honor, he can't -- Mr. Miller cannot answer that question without coming to a legal conclusion on the claim interpretation issue which was presented to Judge DuBois at the Markman hearing and never decided.

JUDGE CHAPPELL: Well, I'm sustaining the objection. First of all, the question asks for him to make some conclusion based on a finding. There was no finding, as we all know, and whether or not mixing

infringed the patent calls for a legal conclusion.

MR. LAVELLE: I understand your ruling.

May I have one additional second to consult, please?

JUDGE CHAPPELL: Yes, you may.

(Counsel conferring.)

MR. NIELDS: Your Honor, may I be heard just briefly on this to raise a point that Mr. Lavelle is not in a position to raise because he wasn't here earlier?

JUDGE CHAPPELL: Any objection?

MS. MICHEL: No, Your Honor.

JUDGE CHAPPELL: Go ahead.

MR. NIELDS: Your Honor, it seems to me pertinent on this issue that we have heard testimony in complaint counsel's case on issues of law from an expert, and that was Joel Hoffman, who testified on FDA law and rendered various opinions on what the law was and what legal consequences would flow from various scenarios. It was pure law, and --

JUDGE CHAPPELL: Did you hear any legal opinions that were allowed after someone objected to a legal opinion?

MR. NIELDS: No, Your Honor, we did not object to it, partly because we understood the Court's opinion

on our motion to dismiss to say, quite clearly, that you were going to regard Mr. Hoffman's opinions and the question of FDA law as an issue of fact in this case, and we think there is an analogy.

Patent lawyers do testify and give legal opinions in patent cases, as we've cited in our response to their motion in limine, which I think the Court has, and we believe that the testimony of this witness will be intelligible and useful --

JUDGE CHAPPELL: I'm sorry, I couldn't hear over the phone ringing, Mr. Nields. You need to repeat that.

MR. NIELDS: I'm sorry, Your Honor.

We believe that this witness' testimony will be way more intelligible and way more useful to the Court if he is permitted to apply the patent principles that he's testified about already and the information which is in the record about the patent case and which he has studied to some legal standard. And again, as Your Honor said I thought at the beginning of this and other times, the weight that you will decide to accord it will be determined later.

We believe, however, that if Your Honor decides this is relevant and appropriate testimony and a relevant line of inquiry, which we believe it is as the

Court knows, you will be in a position to assess it and weigh it only if the witness' testimony can be completed and he can compare the information that he's testified about to some legal standard.

JUDGE CHAPPELL: And you're telling me that there is case law authority for patent attorneys giving opinions, legal opinions in cases?

MR. NIELDS: Yes, there is, and we've cited it in our -- in our motion -- response to their motion in limine, and --

JUDGE CHAPPELL: I didn't see any cases cited under Mr. Miller's -- the portion where you responded to Mr. Miller. I didn't see any citations.

MR. NIELDS: I'm sorry, Your Honor, I had it only a moment ago.

JUDGE CHAPPELL: Well, let's speed things up a little. I'm not going to allow, as I said earlier, legal opinions over an objection, but if you're telling me that there's authority, that this is a unique situation because of patent law, then I will allow the question and answer if we have an objection. I'll allow it subject to reviewing any authority you're going to submit to me.

MS. MICHEL: Your Honor, I would like to clarify how counsel's portraying the law. There was at

one time instances of patent attorneys giving their personal, subjective views on claim interpretation, what a claim meant. There is no authority allowing a patent attorney to testify from the stand on how a litigated case would have been decided or even to give an opinion, his own opinion, on how a litigated case should have been decided. It's quite a different situation.

MR. NIELDS: Your Honor, the authority that we -- that I was referring to is on page 16 of the -- Schering's --

JUDGE CHAPPELL: Well, here's what we're going to do. I'm going to allow the question and answer subject to the parties giving me case cites. I don't want something in a footnote or in a brief. I want case cites, and I'll review the authority, and then I may disregard this answer.

MS. MICHEL: Yes, Your Honor, there are case cites in our brief, several, explaining that legal testimony on issues to be decided by the court is not helpful to the Court and not proper.

JUDGE CHAPPELL: Okay, so you want to stand on -- I'm giving you a chance to submit further authority if you would like. If you don't want to, that's fine.

MS. MICHEL: We will submit further authority, Your Honor.

JUDGE CHAPPELL: Okay, thank you. And we're not allowing a foray into a lot here. We're allowing one question and the answer. We're allowing the question that was pending.

MS. MICHEL: Your Honor, given that Mr. Nields made some discussion here on issues that I'm also not familiar with, Ms. Bokat would like a chance to respond.

JUDGE CHAPPELL: That's fair. Go ahead, Ms. Bokat.

MS. BOKAT: Thank you, Your Honor.

I think Mr. Nields' analogy between Mr. Miller and Joel Hoffman is extremely imperfect. Joel Hoffman was not sitting in that witness chair to give Your Honor a legal opinion. What he did was to merely summarize the existing court opinions and the various proclamations from the FDA in their guidances or their various letters. He was not rendering his own legal opinion, and that's what counsel is asking Mr. Miller to do.

JUDGE CHAPPELL: Thank you.

MS. MICHEL: And Your Honor, if I might add --

JUDGE CHAPPELL: You have my ruling. I'm going

to allow this, but I'm going to decide later whether it's going to be disregarded or not.

MS. MICHEL: Thank you, Your Honor.

JUDGE CHAPPELL: So, do you want the court reporter to read back the pending question?

MR. LAVELLE: If it's possible to do so, yes, Your Honor.

(The record was read as follows:)

"QUESTION: You heard the opinions expressed by Dr. Banker and Dr. Langer on the mixing question, correct?

"ANSWER: Yes.

"QUESTION: In your opinion, what conclusion on infringement flows from the finding that there was mixing?"

THE WITNESS: My conclusion is that that testimony amply supported a finding that there was mixing in the ESI product.

BY MR. LAVELLE:

Q. Okay. And what was your opinion under that hypothetical of whether or not there was going to be infringement?

A. That conclusion leads to the next conclusion, which is that Key had a very strong probability of prevailing on the infringement issue.

Q. Thank you, sir.

Now --

MS. MICHEL: Objection. I move to strike that answer, Your Honor. That was not Mr. Miller's opinion on infringement; that was Mr. Miller predicting how the court would have decided the case.

MR. LAVELLE: Your Honor, I thought that was precisely what you told me you were going to allow.

JUDGE CHAPPELL: I'm overruling the objection. The last two answers are allowed only subject to my ruling to be made later, and I would like the case authorities submitted to my office by the end of the day today or you can hand it to me during court.

MR. LAVELLE: That's fine, Your Honor, we can hand it up to you here in court.

BY MR. LAVELLE:

Q. Can I now direct you back to Exhibit 2060? Do you have that once again?

A. Yes.

Q. And did you reach an opinion as to how the split of the patent life in the ESI settlement compared to your assessment of the likely outcome of the ESI litigation?

MS. MICHEL: Objection, Your Honor, calls for speculation in the sense that he's asking Mr. Miller to

again predict the likely outcome of the litigation rather than give his own opinion on the -- on the merits of the litigation.

JUDGE CHAPPELL: I'm going to sustain it, and what I'm going to do is I think I'm going to take a break and review the case law that the parties have told me they've cited, and I'm going to come back and resolve this one way or the other so I can decide whether to disregard the last few answers that we have.

Does anybody have any further case law they want to submit to me in the next half hour or hour?

MR. LAVELLE: We have --

MR. NIELDS: Your Honor, does the Court now have the -- Schering's response to the motions in limine?

JUDGE CHAPPELL: Yes.

MR. NIELDS: I believe that everything that we wanted the Court to see and wanted to cite to the Court is in that response.

JUDGE CHAPPELL: And I have complaint counsel's motion.

MS. MICHEL: Yes, Your Honor, you have our motion.

MR. NIELDS: Your Honor, the only other thing I can think of which may be pertinent, but I don't want

to burden the Court with it if the Court doesn't view it as pertinent, is I think I referenced in -- orally the other day some class action cases where courts compared the settlement to likely outcome, and I would be happy to provide those citations to the Court --

JUDGE CHAPPELL: I'm expecting to see those in your post-trial brief since that issue is still open.

MR. NIELDS: Okay, okay.

MS. MICHEL: And Your Honor, I would just like -- excuse me, I apologize.

JUDGE CHAPPELL: That's okay. It's happened to all of us. You're doing fine.

MS. MICHEL: To the extent that Mr. Miller would be summarizing the state of patent law and explaining how the evidence in the ESI case fits within that framework of patent law, we don't object, and in that sense his testimony would be like Mr. Hoffman's.

To the extent that he's offering an opinion on the outcome of the case, that can be nothing but speculative and a legal opinion.

MR. LAVELLE: Your Honor, we intend to offer both how the evidence fits in terms of the applicable patent law, and we think it's appropriate and helpful to encapsulate and summarize his opinion, to let him apply those principles to the facts of this case and

testify as to an objective assessment of the case. We think that when you look at the law, you will find what their own expert Mr. Adelman has written that the law on the use of the patent law and procedure experts in patent infringement litigation is that their use is solely within the discretion of the trial judge, and that you will find that the United States Court of Appeals for the Federal Circuit, the Patent Court, has said that as to these types of legal opinions that we're offering, that you have -- you, the Court -- have complete discretion to adopt the opinion as your own, to find guidance from it, to ignore it entirely or to not hear it.

We think you have ample discretion and authority to hear this testimony. We think it will be potentially helpful to you and to perhaps people down the road who have to try to put the pieces together on the merits of the patent case, and we think it would be appropriate and helpful to you so that you should admit it and then determine what weight to give it in your decision-making process.

JUDGE CHAPPELL: Mr. Curran?

MR. CURRAN: Yes. Your Honor, your ruling with respect to this witness might set a precedent that affects Upsher's rights down the road, and so I would

just like to point out on the record that we believe that Mr. Hoffman, Joel Hoffman, the Hatch-Waxman expert for complaint counsel, did provide legal opinions. He interpreted cases that were out there --

JUDGE CHAPPELL: Did you object to those?

MR. CURRAN: No, we didn't, and we expressly stated why we didn't in our response to their motion in limine, and we said we assumed that that would be good for us as well. So, we didn't oppose Professor Hoffman's testimony on the assumption that the same standard would be applied to the respondents' case in chief.

Thank you, Your Honor.

JUDGE CHAPPELL: We don't have any question pending, do we, to the witness? I think I --

MR. LAVELLE: We do not, Your Honor.

JUDGE CHAPPELL: Okay. Let's take a short break, come back on the record at 11:55.

(A brief recess was taken.)

JUDGE CHAPPELL: Who's going to speak for respondents, Mr. Nields or Mr. Lavelle?

MR. NIELDS: I will for the moment, Your Honor.

JUDGE CHAPPELL: Okay. I've done a -- as much of a review as I could have done during the recess of the case law that's been cited by all the parties, and

I understand from your brief, at least as of the early nineties, the court commonly referred to as the Patent Court, the U.S. Court of Appeals for the Federal Circuit, was accepting expert opinions on patent issues. Have they changed that view? Has the law changed in that court?

MR. NIELDS: Your Honor, I am not the best person to answer that question. Mr. Lavelle is a patent lawyer. I can tell you what I believe to be the case.

JUDGE CHAPPELL: That's not a disparaging remark about him, is it? Even under pressure.

MR. LAVELLE: I have been so disparaged before, Your Honor.

The decisions that you have in front of you continue to correctly state the law to the extent that you have discretion to give -- to allow the testimony or not and what weight to give it.

JUDGE CHAPPELL: Ms. Michel?

MS. MICHEL: Your Honor --

JUDGE CHAPPELL: I have looked quickly over the cases that you cited, but -- that's why I asked the question. Do you have any authority to show that the Court of Appeals of the Federal Circuit has changed the law, that they now reject -- I see you cited some

District Court cases. I see one in Utah and one in Pennsylvania.

MS. MICHEL: Your Honor, the Federal Circuit has stated that the issue of claim interpretation is a question of law and that it was for the judge to determine and that expert opinion is not helpful to that determination.

JUDGE CHAPPELL: But they also say that it's the judge's discretion to allow it on patent issues, don't they?

MS. MICHEL: Your Honor, I would point out that there is a big difference between the cases that Mr. Lavelle is relying on and the situation here. The cases have allowed the District Court discretion to allow that testimony -- to allow a patent lawyer, such as -- testimony on his opinion on issues of claim interpretation and to give some background on patent law. Now, the -- it is not within the District Court's decision to abdicate its responsibility in deciding that legal issue. That's a very different situation, though, than what's happening here.

What's happening here is Mr. Miller is giving a conclusion on the likely outcome of patent litigation. No patent lawyer has ever testified in a patent trial on the likely outcome of patent litigation. There's no

authority to support that.

JUDGE CHAPPELL: Okay, I went back and reread my ruling to see if we're derailed how we got derailed, and I said, "If an attorney wants to tell me they looked at a file and they think somebody would have won, I'm going to allow that, and I'll give it the weight it deserves." So, I think Mr. Curran had a better memory than I did of what I had said this morning. To the extent I'm tweaking that ruling, that's what I'm going to do now.

I'm going to allow the witness to tell me he's reviewed the evidence, he's reviewed the file, and he thought it was a good case, as I said this morning. I will not allow a witness to tell me what a judge would have done or what a court would have done. That's not going to be allowed.

And to the extent other legal opinions have come in during this trial, I don't recall any that came in over objection, but in this case, I'm going to go with the case citations I have. And I'll remind the parties, I have a very long memory. If there is anything mis-cited here, that wouldn't be a good thing, and if someone wants to point out if they have made a mistake, I'm going to need to know that in the next day or two, but I'm going to allow it. I understand you've

objected. And I also want to see this issue briefed in the post-trial briefs.

MS. MICHEL: Yes, Your Honor.

JUDGE CHAPPELL: I want to give the parties a chance to give me the latest law they can find and their positions, but I'm allowing it for now. I am going to allow him to tell me what -- you know, he looked at the file and what he thought was going to happen, but I'm not allowing him to tell me, you know, what a judge would have done, what a court would have done, and I'll give it the weight it deserves.

With that, let's proceed, and you may need to re-ask some questions with the -- with the guidelines I've just set out, okay? Thank you, with that, let's proceed.

MR. LAVELLE: Thank you for your ruling, Your Honor.

BY MR. LAVELLE:

Q. Let's go back to the infringement question and just sort of focus ourselves a little bit, okay?

You told us that in your view the term "coating material" should be construed to cover one layer or more than one layer, correct?

A. Yes.

Q. And what is your opinion as to whether or not

the patent's infringed by ESI with that structure?

A. My opinion is that the patent would be infringed by ESI's product.

Q. And would you explain that, please?

A. If the patent term in question is construed to cover a coating material comprising or consisting of one or more layers, ESI's product, based on the facts that I have -- that have been presented by both sides in this case, convince me or persuade me that ESI's product is very likely to be that of a single layer mixture of -- of products -- of components.

However, if the -- if the result were contrary, and that is to say that the two layers were, in fact, distinct, they would still be infringed.

MS. MICHEL: Your Honor, I move to strike the portion of the witness' testimony which gave an opinion as to whether or not the -- there was any mixture in ESI's coating. That is outside the scope of his expertise.

MR. LAVELLE: Your Honor, we obviously think that's just an integral part of forming the opinion that you just permitted him to give.

MS. MICHEL: Your Honor, we would accept Mr. Miller's testimony were it to say that he simply accepts as a hypothetical the issue of whether or

not -- that he simply accepts as a hypothetical the mixing based on the testimony of the technical experts. We object to any testimony by Mr. Miller in which he says, "I conclude that there's mixing." It's -- it's an important difference.

JUDGE CHAPPELL: I sustain the objection as far as this witness telling me his conclusion about mixing, and that part of the answer will be disregarded. Of course, the witness has the right to rely on other opinions, and you have the right to impeach that issue on your cross, Ms. Michel.

MS. MICHEL: Thank you.

BY MR. LAVELLE:

Q. Okay, assume for my next question that there is, in fact, mixing in the ESI product; that is, the ethylcellulose and the HPC are mixed, okay?

A. Yes.

Q. Under that assumption, does the ESI product infringe claim 1 of the '743 patent?

A. Yes.

Q. And would you explain that?

A. Because if the '743 patent is construed to cover mixing or whether it's construed to cover a dual layer system, one or more layers, then either way, ESI's product comes within the literal scope of the

claim.

Q. Is there a concept in patent law called "literal infringement"?

A. Yes.

Q. And what is that concept, sir?

A. Literal infringement is where an accused product contains elements each of which is literally found within the recitation of the claim elements on a one-to-one basis.

Put another way, each element recited in the claim finds an exact literal counterpart in a corresponding component in the accused product.

Q. Thank you.

If the term "coating material" is construed to cover one or more layers in the coating, is claim 1 literally infringed by ESI's product?

A. Yes.

Q. If the facts are that ESI's product is mixed, is claim 1 infringed by ESI's product?

A. Yes.

Q. Okay. Is there a doctrine in patent law called the doctrine of equivalents?

A. Yes.

Q. And would you explain to the Court what that doctrine is?

A. The doctrine of equivalents is the application of the principle that when a product fails to meet each and every limitation recited in a patent claim, because there is one element or more elements, but let's say one element or component in the accused product that does not literally correspond to an element in the claim, then the inquiry is does that difference in elements or does the element that is in the accused product which is not literally recited in the claim correspond substantially to the claim element in the sense that it would do the same thing in the same way to give the same result.

In other words, that looking at the claim element and the corresponding element in the product, are they insubstantially different? If they are not -- if they are insubstantially different, no substantial difference, then we say that there is equivalence between the accused product and the claim recitations.

Q. Okay. And if the facts support the conclusion that the HPC in ESI's product was doing the same thing as the HPC in the patent claim, modifying the film, would that be relevant to infringement under the doctrine of equivalents?

A. Yes.

MS. MICHEL: Objection. This testimony goes

outside the scope of the witness' expert report. He provided no opinion on infringement under the doctrine of equivalents in his expert report.

JUDGE CHAPPELL: Is that right?

MR. LAVELLE: Yes, that's right, Your Honor.

JUDGE CHAPPELL: What she's saying is right, you've gone beyond the scope of what you disclosed in discovery to complaint counsel?

MR. LAVELLE: He did not offer an opinion on the doctrine of equivalents in his report, that's true.

JUDGE CHAPPELL: That objection sustained.

BY MR. LAVELLE:

Q. Would you explain why you didn't offer any opinion on the doctrine of equivalents in your report?

A. Well, in assessing the evidence on both sides, I did not consider the equivalency issue to be a significant one or a material one to the outcome of the case.

Q. Would you explain that, please?

A. Because the interpretation that would be given to claim 1 of the '743 patent was one which would literally encompass the ESI product, so that it would not be necessary to extend the inquiry beyond the determination of literal infringement. If the claim is literally infringed, one need go no further.

MS. MICHEL: Objection, Your Honor. I'm going to move to strike in that I believe that the witness is now giving testimony as to -- when he uses terms like "would have," he's now trying to predict the outcome of the patent litigation that was settled rather than giving his own -- his own personal views on the patent merits.

MR. LAVELLE: Your Honor, he was asked to explain his conclusion, and he was doing so.

JUDGE CHAPPELL: I'm not sure it goes so much to the "would have," Ms. Michel. I overrule the objection.

BY MR. LAVELLE:

Q. So, in your analysis, were the doctrine of equivalents issues material to the outcome of the infringement issue you looked at?

A. No.

Q. And you heard testimony here in the courtroom yesterday at length about how the HPC works in the ESI product. Do you recall that testimony?

A. Yes.

Q. If there's literal infringement, is any of that testimony material to the outcome of the infringement question?

A. No.

Q. Did you hear testimony at length about how the HPC works and whether or not it forms pores or channels or hydrated layers or anything else, did you hear all that testimony?

A. Yes.

Q. If there's literal infringement, is any of that testimony relevant to the infringement question?

A. No, it's not.

Q. And would you have to resolve any of those fact disputes in order to find literal infringement?

A. No.

Q. And did you hear extensive testimony about the shape of the potassium crystals and whether or not they compress and whether they're round or pin-shaped or something else? Did you hear that testimony yesterday?

A. Yes.

Q. Any of that testimony relevant to the question of literal infringement?

A. No.

Q. What was your ultimate conclusion on the question of infringement in the ESI case? I'm sorry.

What was your ultimate conclusion on the question of whether or not ESI infringed the '743 patent?

A. My conclusion is that ESI literally infringed

the '743 patent.

Q. Okay, very good.

Could I direct you now back to Exhibit 2060, please.

A. Yes.

Q. And we've talked about this exhibit a little bit. Could you just re-orient us again on what this exhibit shows?

A. This is a time line showing points in time between the January 1998 settlement in principle between Key and ESI at one end, going forward to January 2004 when, pursuant to the settlement agreement that was arrived at, ESI would be permitted to enter the U.S. market with its generic version of the -- generic version of Micro-K KCl tablets.

Q. And -- I'm sorry.

A. And -- and the blue portion of the time line, from the January 2004 time point to the end, represents the period remaining in the life of the patent until September 2006 when the patent will expire.

Q. And under the settlement agreement, how much sooner does ESI get a license than if the case had gone through and there had been a finding of infringement?

A. By my calculation, the period in question that you're referring to, which is the blue period, is

approximately 32 months.

Q. Okay. How does the split of the patent life contained in the ESI settlement compare to the assessment of the merits of the ESI case?

A. I think it is at least a fair representation of the likely outcome of the case; that is to say, by -- in my assessment of Key's chances of prevailing were very high, this would be a generous -- a relatively -- at least a generous arrangement whereby 32 months would be added to the period prior to the expiration of the patent during which time there could be sales of Micro-K tablets in the United States.

MS. MICHEL: Your Honor, I object to the witness' answer as nonresponsive to the extent that it gave testimony on the likely outcome of the case rather than his own personal views of the strength of the merits, and also I believe that his testimony on the likely outcome of the case is improper under your ruling, that he would not be allowed to testify as to what any court might have decided.

MR. LAVELLE: Your Honor, I think we're trying to parse his words a tad too fine. He's clearly testifying about his comparison of the split against his assessment of the merits.

JUDGE CHAPPELL: Well, I am going to overrule

the objection, but I am going to instruct the witness to listen to the question and answer the question that's asked only. You seem to be rambling a little bit and going on to more things than asked.

THE WITNESS: Yes, Your Honor.

BY MR. LAVELLE:

Q. Let me just ask it once again clearly.

Would you compare the split of the patent life in the ESI settlement to your assessment of the merits of the ESI case?

JUDGE CHAPPELL: Didn't you just ask that?

MR. LAVELLE: I'll withdraw the question, Your Honor.

JUDGE CHAPPELL: I mean, if it's a different question, fine, but we don't need the same question asked again.

MR. LAVELLE: Your Honor, it was only slightly different, and I was trying to sort of cooperate and get an answer that would fall within your instruction.

JUDGE CHAPPELL: Okay, good.

Susanne, read the question back. I'll allow it.

(The record was read as follows:)

"QUESTION: Would you compare the split of the patent life in the ESI settlement to your assessment of

the merits of the ESI case?"

THE WITNESS: My comparison of the split with my assessment of the ESI case is that they are fairly represent -- fairly in line with each other.

MR. LAVELLE: Thank you, Your Honor, I have nothing further.

JUDGE CHAPPELL: Okay. Cross?

MR. LAVELLE: Oh, Your Honor, I'm sorry, nothing further with respect to the ESI case. We may recall Dr. Miller with respect to the Upsher case.

JUDGE CHAPPELL: Ms. Michel, I don't think you need to go over what you've already asked on voir dire of the witness. That's part of the record.

MS. MICHEL: Thank you, Your Honor.

JUDGE CHAPPELL: And I wanted to remind the parties also, regarding these expert opinions, if you look at the history of the Federal Rules, these rules are designed to protect the jury from hearing things they are not supposed to hear. We don't have a jury. Because something is allowed here, it's not the end of the world for either side. I'm going to give things the due weight that's deserved. We've got a record here. I'm going to see the questions that are asked by both sides when you qualify a witness and when you impeach a witness. Just my thoughts.

You may proceed.

CROSS EXAMINATION

BY MS. MICHEL:

Q. Mr. Miller, with regard to the exhibit currently on the screen, which I believe is marked SPX 2060, I believe it was your testimony that the split of the patent life there -- I'm sorry if I mischaracterize this -- was a fair comparison to your assessment of the merits of the ESI case. Is that right?

A. Yes.

Q. So, would you agree with me that the yellow line here, the line that shows the amount of time before ESI can enter, is approximately 75 percent of the total length of the line? Is that right? Or please give it your own number.

A. Starting from January 1998 to January 2004, it appears to be 72 months in comparison with 32 months between January 2004 and September 2006, whatever that ratio is. 72 -- the total number of months would be -- 72 is -- is 104 months, so I would say that the yellow portion of the time line would correspond to about 74 months, 75 months -- 74 percent or so of the total time line.

Q. All right. Now, you would agree, Mr. Miller, that you don't think that anyone can quantify the odd

that one party will win a patent litigation because of the unpredictable nature of that litigation -- of patent litigation. Isn't that right?

A. Attorneys are often asked by their clients to do just that, to quantify the probability of being able to prevail or not prevail in the litigation. In this particular situation, we have a record that -- of what essentially was going to be presented to the District Court had the case gone to trial, and while I would say that one cannot quantify with 100 percent precision, I'd say that one can -- one can obtain a fairly accurate sense of how the case would have come out.

Q. Mr. Miller, I would direct your attention to page 62 of your deposition, which you can look at on the screen or it's the second tab in the binder there, and specifically your question -- there was a question:

"QUESTION: They might be 80 percent, they might be 20 percent," and in this context we're talking about the chances of winning litigation, patent litigation.

And you responded: "I would not be prepared to give you -- I don't think anyone could quantify the odds on something like this. Litigation being of the nature that it is, you know, you can assess the merits of a case in a general sense, but to be specific on a

number, I would -- I could do it, but, you know, I would feel more comfortable by saying that it was substantially or better than 50 percent."

That was your testimony regarding the Upsher litigation.

A. At that time of my deposition, yes.

Q. So, Mr. Miller, your testimony would be then that Schering had -- I believe you quantified the split of the patent life as about 70/30. Is that right?

A. Yes.

Q. So, it would be your assessment of the merits of the patent litigation, then, that there was at least a 70 percent chance that Schering was going to win that litigation.

A. If I'm asked to quantify, which I -- you know, I might not be able to do with that degree of precision, I would say that ESI's chances of prevailing were much better than -- well, substantially better than 50 percent and, in fact, I would say they were probably at least as good as 70 percent and perhaps more.

MR. LAVELLE: Could I hear that answer read back, please?

THE WITNESS: Did I say ESI? Sorry.

(The record was read as follows:)

"ANSWER: If I'm asked to quantify, which I -- you know, I might not be able to do with that degree of precision, I would say that ESI's chances of prevailing were much better than -- well, substantially better than 50 percent and, in fact, I would say they were probably at least as good as 70 percent and perhaps more."

THE WITNESS: It should be Key instead of ESI there. Sorry.

BY MS. MICHEL:

Q. Mr. Miller, let me ask you for a moment to assume that ESI had a stronger case than you believe and that therefore correspondingly Schering had a weaker case than you believe. Under this theory, then, of the patent merits reflecting the split, wouldn't it be true that ESI should have obtained an earlier entry date?

A. That would seem to be the case, yes.

Q. So, if ESI did not get an earlier entry date in that situation, then one way for Schering to make up for that lost time to ESI is to pay ESI money. Isn't that correct?

MR. LAVELLE: Objection, Your Honor, outside the scope of his testimony on direct.

MS. MICHEL: Your Honor, the witness has

testified that the patent merits in his view reflect a split of the patent life --

JUDGE CHAPPELL: I agree. Overruled.

BY MS. MICHEL:

Q. Would you like the question read back?

A. Yeah, I didn't understand the question.

(The record was read as follows:)

"QUESTION: So, if ESI did not get an earlier entry date in that situation, then one way for Schering to make up for that lost time to ESI is to pay ESI money. Isn't that correct?"

THE WITNESS: I have no basis for giving -- I have no way of giving an answer to that question. I don't know what you mean by -- by "giving money." This was a settlement that was embodied in the form of a document that gave ESI a nonexclusive royalty-free license to market its product in the United States beginning in September 2004. Beyond that, if you're asking me about the economics or the financials of it, I can't -- I can't speak to it.

BY MS. MICHEL:

Q. Mr. Miller, you're aware that part of the settlement agreement, which you read, requires Schering to pay ESI a sum of money. Isn't that right?

A. Frankly, ma'am, I haven't read the agreement

other than with respect to what the settlement provides with regard to the split of the license term. I did read the agreement, but right now, sitting here, I have not -- no recollection of any of the other details of that license agreement, because that was not part of my assignment, to become involved in other tangential or other matters respecting the two companies.

Q. So, is it fair to say then, Mr. Miller, that nothing in the testimony you offered today takes into account the amount of money required -- excuse me.

Is it fair to say, Mr. Miller, that your testimony today does not take into account in any way the money which the agreement requires Schering to pay to ESI?

A. That's right, I did not take that into account.

Q. Thank you.

Mr. Miller, we can't here create the hearing and the trial that would have occurred in the ESI patent case, can we?

MR. LAVELLE: Objection, Your Honor. I think this was gone into in the voir dire. Asked and answered.

MS. MICHEL: Your Honor, I -- this will actually take a somewhat different tack.

JUDGE CHAPPELL: I'm going to allow it. I

don't remember everything that was asked. It's been an eventful morning. If she needs to go back and ask a question again, I'm going to allow it. Overruled.

MS. MICHEL: Could you reread the -- read back the question, please?

(The record was read as follows:)

"QUESTION: Mr. Miller, we can't here create the hearing and the trial that would have occurred in the ESI patent case, can we?"

THE WITNESS: It never happened, so there's nothing to re-create.

BY MS. MICHEL:

Q. ESI no longer has any motivation, as it did in the patent case, to demonstrate that its product doesn't infringe, does it?

A. Assuming the license agreement remains in effect for the duration of the patent term and that there is no dispute between the parties, which I have no way of predicting, that would be speculation as to what would go on in the future between them, I don't know why there would be an issue regarding whether or not ESI infringed with respect to a specific product that was at issue if the settlement agreement gave ESI a nonexclusive royalty-free license. So, I have no way -- I clearly have no way of answering that question

with any kind of precision. I'm sorry.

Q. My question was actually more simple than that. My question was ESI no longer has any motivation to demonstrate that its product doesn't infringe because the patent litigation has been settled.

A. I'm not aware that it was settled with a consent judgment of infringement. I understand that it was settled with this settlement agreement. Any issues that might arise in the future regarding ESI -- a position that ESI might choose to take, I have no way of knowing.

Q. Mr. Miller, can you conceive of any reason why at this point ESI might want to demonstrate that its product does not infringe?

A. Not off -- no, I cannot. Sitting here right now, I can't.

Q. Now, ESI was prepared to call fact and expert witnesses and enter exhibits to support its case at a patent trial, wasn't it?

A. Yes, they were -- I'm sorry, read the question again, please.

(The record was read as follows:)

"QUESTION: Now, ESI was prepared to call fact and expert witnesses and enter exhibits to support its case at a patent trial, wasn't it?"

THE WITNESS: I would expect that would have been the case, yes.

BY MS. MICHEL:

Q. And we can't produce all the same witnesses with all the same motivations in this proceeding, can we?

A. Totally and completely, I don't think so. I don't think we can. In this proceeding, no.

Q. And certainly we can't have the same judge deciding the patent issues, can we?

A. I don't think that would be a realistic expectation.

Q. Now, Mr. Miller, you claim to give an objective assessment of the patent merits. Is that right?

A. Yes.

Q. The opinion that you gave on the patent merits is your opinion, correct?

A. The report?

Q. The opinion that you offered here today, that's your opinion.

A. That's my opinion, yes.

Q. And we can't test that opinion by comparing it to the outcome of the litigation, can we?

A. There's nothing to compare it with the outcome -- there was no outcome of the litigation with

respect to the trial of the case. There was no trial.

Q. So, we have no way to test the objectivity of your opinion, do we?

A. Well, there's no way to -- well, there's nothing that I can tell you that would indicate that I was anything other than objective. My assignment as an expert witness in these proceedings was to make an objective assessment of the merits of the case. I was not retained to serve as an expert witness on behalf of Schering's positions, whatever they were, in these proceedings.

JUDGE CHAPPELL: Sir, I need you to answer the question that was asked, please.

Susanne, would you read back the question?

(The record was read as follows:)

"QUESTION: So, we have no way to test the objectivity of your opinion, do we?"

THE WITNESS: I suppose not.

BY MS. MICHEL:

Q. Thank you.

Now, during the Markman hearing in the patent litigation, the court took testimony from Dr. Banker for Schering and Dr. Hopfenfeld (sic) for ESI. Is that correct?

A. Yes.

Q. A central issue in the Markman hearing was the meaning of the term "a coating material" in the claim, correct?

A. Yes.

Q. And specifically whether the definition of "a coating material" requires that ethylcellulose and hydroxypropylcellulose are -- or PEG, polyethylene glycol, must be mixed, correct?

A. May I have the question again, please?

(The record was read as follows:)

"QUESTION: And specifically whether the definition of "a coating material" requires that ethylcellulose and hydroxypropylcellulose or PEG, polyethylene glycol, must be mixed, correct?"

THE WITNESS: That was an issue, yes.

BY MS. MICHEL:

Q. The parties didn't submit any additional information to Judge DuBois on the claim interpretation issue following the Markman hearing, did they?

A. I don't believe so.

Q. To the best of your knowledge, if we wanted to review all the information and the arguments that the judge had on claim interpretation, we should review the briefs submitted by the parties on the issue, the Markman transcript and the exhibits associated with

those two things, correct?

A. Yes.

Q. So, if we were trying to put ourselves in the judge's shoes and guess how he was going to decide the claim interpretation issue, we would get the most accurate picture possible from the record -- from that record, correct?

A. That was the record we had -- I had to work with, yes.

Q. And in that -- if we were trying to put ourselves in Judge DuBois' shoes, we should only consider arguments that he heard, right?

A. Arguments and evidence placed before the judge, yes.

Q. And so the arguments on claim interpretation that were made in this courtroom yesterday and the day before, those arguments -- that -- those -- this proceeding was not before Judge DuBois, was it?

A. Yesterday's proceeding was not, no.

Q. So, the testimony given here by Dr. Banker and Dr. Langer and you on the likely interpretation of the claim, that could just -- that could have no bearing on Judge DuBois' decision.

A. What transpired in these proceedings would have no bearing on his decision if he had made one. He

didn't make one. He wasn't -- and that was years ago.

Q. And the proceedings of this Court could have no bearing on the likely outcome of that litigation, correct?

A. Yes, logically you're right.

Q. Now, in their testimony during the Markman hearing, Dr. Hopfenfeld (sic) and Dr. Banker discussed a number of other patents and technical articles, and the parties submitted those into evidence. Isn't that right?

A. Yes. It's Hopfenberg. It's Hopfenberg, and yes, they did.

Q. Thank you. And you didn't explain here in your testimony regarding claim interpretation the significance of each of those points that was raised by Dr. Hopfenberg and Dr. Banker, did you?

A. May I have the question, please?

(The record was read as follows:)

"QUESTION: And you didn't explain here in your testimony regarding claim interpretation the significance of each of those points that was raised by Dr. Hopfenberg and Dr. Banker, did you?"

THE WITNESS: Right.

BY MS. MICHEL:

Q. Okay. You've not presented Dr. Hopfenberg's

analysis or given any assessment, have you, today?

A. Today? No.

Q. So, you didn't give us an accurate picture today of what Judge DuBois heard, did you?

A. No, that's not correct. I did not specifically testify on the items that you mentioned; however, the answers that I gave were derived from my consideration of those materials when I was undertaking this assignment, when I reviewed the record. I did review those materials.

Q. Now, Dr. Hopfenberg testified at the Markman hearing on how one of skill in the art would understand the term "coating material." Isn't that right?

A. Yes, I believe he did.

Q. And Dr. Hopfenberg testified that a coating which was applied in separate layers, a layer of ethyl -- a layer of EC and a layer of HPC on top of it, if applied by the spray coating process could not work to give sustained release. Is that right?

A. I believe he testified something to that effect, yes.

Q. And the judge indicated during the Markman hearing, didn't he, that he saw the issue of whether a product with separate layers of EC and HPC would work, the judge saw that issue as relevant to the claim

interpretation issue, didn't he?

A. He mentioned it in connection with the -- during the Markman hearing. Whether -- whether I take that -- those comments of the judge to be connected with his determination of what the claim means is I don't think so. The issue of whether the claim would work or not has to do with whether the claim is valid or not, and that was not the purpose of the Markman hearing. The Markman hearing was to interpret the claim.

Q. Rachel, if you could help me find the Markman transcript, please.

Mr. Miller, you can turn to your binder to the tab marked CX 1659, please, and specifically I would direct your attention to page 126.

A. I'm sorry, what's the exhibit number?

Q. I believe it's marked CX 1659. It may be towards the back. And it will be in the black binder, the one --

A. This one here?

Q. Yes, thank you.

Oh, I apologize, it's marked SPX -- the exhibit number that I've directed Mr. Miller's attention to is SPX 687, and specifically I'd like to direct your attention to page 126, line 25, and continuing on to

page 127, and let me read -- this is the Court talking beginning at line 25 of page 126:

"THE COURT: I can tell you that I don't think the issues are free from doubt. I don't know whether I've raised an issue that you haven't considered. The issue that I articulated with you, Mr. Herman, and that is whether assuming the patent is broad enough to be read -- and I'm referring to the claim portion of the patent -- is broad enough to be read as including separately layered coatings of these three substances and the molecular weights described in the patent.

"The question whether that will work and whether someone of ordinary skill in the art reading that would know or would not know that it would not work, that's an issue that occurred to me as I sat here. I don't know whether you have focused on it. We'll address that later.

"In any way -- in any event, it seems to me that this is far from a clear issue, and I launch you with that thought. This is not a slam-dunk case. I haven't made up my mind."

The judge at this portion of the transcript is giving some indication that he considers this issue of whether the coatings would work with two separate layers as an important -- as an issue relevant to claim

interpretation, isn't he?

A. I'm not sure. I know he -- I read what he said, and he is posing a concern that if the claim were interpreted to cover two layers, whether it would read on something that would work. There is no evidence in this case that -- at all that such a product would not work, and he would -- was concerned with whether a claim interpretation that read on an inoperable embodiment that was not even shown to have been enabled by the patent was something that he would ultimately have considered in this case.

The issue was whether or not the claim is broad enough -- whether or not the claim reads on a material -- a coating material that contains a mixture of the two ingredients or whether the two -- as well as the two ingredients being in separate layers. That was his -- that was his issue for determination at the Markman hearing. He's getting off into another concern of his as to whether the claim, if it covered two layers which were absolutely separately and distinct from each other, would work. He's raising it as a concern for him and what may have been an issue of bona fide contention, but there was no evidence on this particular point.

Q. So, you're saying then, Mr. Miller, that the

judge has indicated some concern in this passage that perhaps the patent is invalid if it's read as broadly as Schering was requesting?

A. That was -- that may have been a concern that he was expressing, yes. That's what he said.

Q. Okay, let's talk about the trial for a minute. Now, the issue of claim interpretation that was presented at the Markman hearing is a question of law, correct?

A. Yes.

Q. And the issue of whether or not the claim as construed can be -- covers ESI's product, that's a question of fact, correct?

A. Yes.

Q. And the main point of contention on this factual issue was whether or not the EC and HPC were actually mixed in ESI's product, right?

A. Yes.

Q. And that issue was going to be presented at trial, correct?

A. I expect it would have been presented at trial, yes.

Q. Okay. And unlike the claim interpretation where we have a completed Markman transcript, we don't have a trial transcript, do we?

A. No.

Q. And so again, we don't know what witnesses would have been presented on those issues and what they would have said, do we?

A. No.

Q. Over the last two days, we heard Dr. Langer and Dr. Banker testify that ESI's product did have at least partial mixing, didn't we?

A. Yes.

Q. But that testimony was never presented to Judge DuBois.

A. At the Markman hearing, no.

Q. That testimony was never presented to Judge DuBois at any time, was it?

A. I believe that's correct.

Q. Now, ESI's expert, Dr. Hopfenberg -- Hopfenberg -- he would have testified at trial that the ethylcellulose and HPC were not mixed in ESI's product, wouldn't he?

A. Say that again, please.

Q. I'll rephrase that.

ESI's expert Dr. Hopfenberg would have testified at trial that the EC and the HPC were not mixed in ESI's product, wouldn't he?

A. Presumably, yes.

Q. But Dr. Hopfenberg had no reason to present that testimony here, did he?

A. At the Markman hearing?

Q. In this proceeding, excuse me. Dr. Hopfenberg has no reason to present -- to present the testimony that he might have presented at trial in this proceeding, does he?

A. When you say "this proceeding," this one here?

Q. This proceeding, yes, exactly.

A. I don't understand the question.

Q. My question is, you agree with me that Dr. Hopfenberg would have presented testimony at the trial if it had gone forward on the issue of whether or not the EC and the HPC were mixed. Isn't that correct?

A. It is likely he would have done that, yes.

Q. And Mr. --

A. Now, may I speak?

Q. Yes.

A. Now, the -- whether the case would have gone to trial I think would have been dependent upon the outcome of the Markman hearing, which as you know was not decided. Also, I note that --

Q. Excuse me, there's no question pending, Mr. Miller.

A. Okay.

MR. LAVELLE: Your Honor, if he was explaining his answer, I think he should be permitted to.

MS. MICHEL: I think he answered my question sufficiently.

JUDGE CHAPPELL: Was that an objection?

MR. LAVELLE: It was just a request that he was in the middle of being permitted to -- if he was in the middle of explaining his answer, he be permitted to finish it.

JUDGE CHAPPELL: Well, he asked if he could speak, and he did, and then he went on to another topic when he said, "Also, I note that," and she has the right to cut him off.

BY MS. MICHEL:

Q. Mr. Miller, in concluding that ESI's product literally infringed, you relied on Dr. Langer's testimony that the ethylcellulose and the HPC were mixed to some extent, as you stated in your report. Isn't that right?

A. I didn't rely on it. I considered it together with the other evidence in the case. I'm persuaded that what Dr. Langer adduced was -- was the correct thing.

MS. MICHEL: Your Honor, I move to strike the witness' last answer in that you've already ruled that

he's not competent to give an opinion on whether or not there was mixing. It's outside the scope of his expertise.

MR. LAVELLE: Your Honor, she asked him a question as to whether or not he relied on Langer, and he explained what he did.

JUDGE CHAPPELL: She asked if he relied on it. I'm striking -- I'm going to disregard the part of the answer after "I didn't rely on it." Proceed. So, the objection is sustained.

BY MS. MICHEL:

Q. Now, Mr. Miller, in your report, you stated that you -- Dr. Langer's opinion was that the EC and the HPC were mixed to some extent, correct?

A. I believe so.

Q. So, when you gave an opinion on infringement based on that understanding of Dr. Langer's testimony, you were not basing your infringement opinion on any testimony by Dr. Langer that there was homogenous mixing throughout the coating. Is that right?

A. I considered that -- that testimony in my -- in my report, and when I said, if you read my previous answer back, I think to some extent, and that included some or all of it was mixed.

Q. Does your opinion on infringement require that

there be homogenous mixing in the coating, assuming for a moment that the term "coating material" requires homogenous mixing?

A. I don't understand that one.

MS. MICHEL: Could you read back the question, please, and I'll try again.

(The record was read as follows:)

"QUESTION: Does your opinion on infringement require that there be homogenous mixing in the coating, assuming for a moment that the term 'coating material' requires homogenous mixing?"

BY MS. MICHEL:

Q. All right, I'll withdraw that question.

Mr. Miller, does your opinion on claim interpretation -- let me withdraw that.

Assuming Judge DuBois had ruled that the term "coating material" required that there be mixing, do you understand ESI had to have been arguing that the term "coating material" required homogenous mixing?

A. May I have the question back, please?

(The record was read as follows:)

"QUESTION: Assuming Judge DuBois had ruled that the term 'coating material' required that there be mixing, do you understand ESI had to have been arguing that the term 'coating material' required homogenous

mixing?"

THE WITNESS: I don't know how to answer that question. I'm not -- I'm sorry.

BY MS. MICHEL:

Q. Do you understand ESI to have been arguing at the Markman hearing that the term "coating material" required homogenous mixing of the ethylcellulose and the HPC?

A. In the claim?

Q. In the claim, yes.

A. Yes.

Q. Now, if Judge DuBois had accepted ESI's position and ruled that the term "coating material" required homogenous mixing, would you agree with me that only partial mixing would not satisfy a term literally requiring homogenous mixing?

A. Not necessarily, because the way the claim reads with respect to the term "coating material," if the court required that the coating material be interpreted to mean a mixture, then the claim has no limitation in it regarding to what extent there be a mixture. If there are two layers applied in -- if the layers were applied in sequence, as was the case in ESI's methodology for making the product --

Q. Mr. Miller, I'm afraid you're going beyond the

scope of my question at the moment.

A. I'm trying to answer the question.

Q. Let me ask you, you're -- the answer that you just gave assumed that the court would issue a claim interpretation which required mixture of the EC and HPC but not homogenous mixing. Isn't that right?

A. Right, right.

Q. All right. Now, I am asking you to assume a hypothetical --

A. Yes.

Q. -- in which Judge DuBois accepted the position presented by ESI and held that the claim required homogenous mixing.

A. Right.

Q. If the court ruled that the claim terms requiring homogenous -- required homogenous mixing, would a coating having only partial mixing infringe that claim?

A. I believe so, because the claim -- the claim is open-ended, and the word "comprising" appears in that claim, and if it comprises a coating and the coating is characterized as containing a mixture, it doesn't limit the claim to one in which the -- the only form in which the HPC and EC would be present would be in that mixture.

Q. Mr. Miller, I'm asking you to assume a hypothetical in which the claim -- in which the court has interpreted the claim to require at least one layer which contained a homogenous mixture of HPC and EC.

A. Right.

Q. Now, if ESI's product had no layers containing a homogenous mixture of HPC and EC, could that product have literally infringed the claim?

A. No.

Q. Thank you.

Let's put up the claim, please, and I believe you can find the patent at CX 12.

Your Honor, I suspect I only have five to ten minutes left in the sense of if you're considering a lunch break or whatever, I can just press forward.

JUDGE CHAPPELL: We're going to break around -- sometime after 1:15.

BY MS. MICHEL:

Q. Rachel, if you could please go to the claim in column 8 and expand it, please. All right, and Rachel, could you expand the paragraph that begins "A coating material" in claim 1.

Now, there's been a lot of discussion about this term "a coating material," and I believe it was your testimony that the term "a coating material" here,

that the plain language understanding of that term would -- would suggest that separate layers of HPC and EC were encompassed within the interpretation of "a coating material." Is that right?

A. Yes.

Q. Now, isn't it true, Mr. Miller, that -- excuse me for a moment.

Now, Mr. Miller, isn't it true that the patent itself, including the claims and the specification and the prosecution history, are the most legally significant or the most legally -- the most significant source of legally operative meaning of a disputed claim term?

A. Yes.

Q. So, would you agree with me then that claim interpretation always requires some review of the specification?

A. Yes.

Q. Now, would you agree with me that at at least one place in this patent, the specification describes the potassium chloride crystals as being coated with a polymeric mixture of EC and HPC?

A. I don't recall the specific place, but I do recall that that word -- that that phrase does appear, yes.

Q. And would you agree with me that the manufacturing process described in the specification could only result in a coating that had a mixture of HPC and EC?

A. Yes.

Q. Would you agree with me that all of the examples described in the specification have potassium crystals coated with a material which is a mixture of EC and HPC?

A. Yes.

Q. Now, looking -- turning back to the claim language, it recites, "a coating material for individual potassium chloride crystals, the coating material comprising ethylcellulose," and then it goes on, "hydroxypropylcellulose."

So, in this term "a coating material," "material" is a noun here, isn't it?

A. Yes.

Q. And "coating" is an adjective. It describes the kind of material, doesn't it?

A. I'm not sure it's an adjective. You could read it that way. I read it as being one -- a collective -- a two-word noun, "a coating material."

Q. You agree with me it's possible, even looking at the plain language of the term "coating material,"

to describe the word "coating" here as an adjective, though. It's possible you said.

A. It's possible, yes.

Q. So, what this claim describes -- so, what this claim recites is a coating material -- a coating material which has at least two components, ethylcellulose and HPC. Is that right?

A. I would prefer to use the term "comprising EC and HPC."

Q. All right. And the term "comprising," when used by patent lawyers, means that we can add in other things. There can be other things, but there's got to be at least what follows the term "comprising." Is that fair?

A. Yes, yes.

Q. So, what we have here and what we're debating is the plain meaning of the term "a coating material comprising two components," right?

A. Yes.

Q. Now, if I have one material and it has two components, would you agree with me that the plain understanding of that term is that those two components have to be mixed so that the material will have only one characteristic?

A. No.

Q. And would you agree with me that if I have two separate layers, that I have two materials?

A. No.

Q. And would you agree with me that if I have two layers and each of those layers has a different composition and different characteristics, that I have two materials?

A. In the context of this claim or in general? If you're asking me in the context of this claim, I read the word "coating material" as not being limited to one -- to one layer.

Q. Let me ask you in general, then. Would you agree with me that if I have two layers and each layer has a different composition and different characteristic, that the general understanding of the word "material," outside the context of this claim, would be that I have two materials?

A. I can't answer the question unless there is a context.

Q. Okay. Now, there was some debate about whether or not this claim can cover coatings -- a product having one layer or two layers. Is that right?

A. Repeat the question, please. I mean, have it read back.

(The record was read as follows:)

"QUESTION: Now, there was some debate about whether or not this claim can cover coatings -- a product having one layer or two layers. Is that right?"

THE WITNESS: With respect to the term "coating material," yes.

BY MS. MICHEL:

Q. So, with respect to the -- so, the issue of -- let me ask you this:

The issue of whether or not there could be one layer or two layers in the product, in the coating on the product, doesn't address the issue of the meaning of the term "a coating material."

A. I think you have it backwards. You first -- you first address the meaning of the word "coating material," and then you compare it with whatever you want to compare it with. You determine the meaning of the word "coating material," and my assessment of the evidence and the arguments presented on both sides is that the coating material is not to be limited to a homogenous mixture. It may include that, but it is not necessarily -- it is not necessarily limited to it. And there's no evidence in the patent that says it is. None whatsoever.

Q. And there is no evidence in the patent or the

prosecution history ever referring to a coating material as two separate layers of two chemically distinct materials. Isn't that right?

A. The absence of that language does not preclude --

Q. It was a yes or no --

A. -- the interpretation of the claim to include that.

Q. -- it was a yes or no question.

There is nothing in either the specification or the prosecution history, whichever refers to the term "a coating material," as encompassing two chemically distinct materials.

A. In ipsissima verba, you're right, correct.

Q. Thank you.

I have nothing further, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. LAVELLE: Yes, if I could just have one moment.

JUDGE CHAPPELL: Okay.

(Counsel conferring.)

MR. LAVELLE: I just have a couple of questions, if I could, Your Honor.

REDIRECT EXAMINATION

BY MR. LAVELLE:

Q. Well, first of all, you were asked some questions about whether or not Dr. Hopfenberg could have been here, and let me just ask you first of all, do you know of any reason why -- strike that. Let me just move on.

The documents that you reviewed in reaching your conclusion, were they documents that are available to all -- to both of the parties in this case or all three of the parties in this case?

A. That would be my understanding, yes.

Q. Okay. And the deposition testimony that you relied on, was that deposition testimony that's available to all of the parties in this case?

A. I believe so.

Q. And --

A. Yes.

Q. -- the pleadings and other papers you relied on, they are available to all of the parties in this case?

A. Yes.

Q. And the law that you applied, did you apply any sort of secret rules or was it generally available patent law principles?

A. Patent law principles in citable decisions.

Q. And did you, in fact, cite statutes and law in

your report?

A. Yes.

Q. And somebody could look up those statutes and laws and see if you cited them correctly, I suppose, right?

A. Yes.

Q. And if one of my partners wanted to analyze it and see if they came to the same objective conclusion as you, there's no reason they couldn't do that, is there?

A. No.

Q. Okay. And if the Federal Trade Commission wants to review the facts and the law and apply the law to the facts, they can do that and come to the same -- come to a conclusion about whether they have the same conclusion as you, correct?

A. Yes.

JUDGE CHAPPELL: Mr. Lavelle, I'd rather hear his testimony than yours. Let's try not to lead the witness so much.

MR. LAVELLE: I don't have anything else, Your Honor, thank you.

JUDGE CHAPPELL: Well, did he answer that one?

THE WITNESS: I said yes.

JUDGE CHAPPELL: Okay.

Recross?

MS. MICHEL: Recross, Your Honor.

RECROSS EXAMINATION

BY MS. MICHEL:

Q. Mr. Miller, you didn't review any pretrial briefs, did you?

A. In this case?

Q. You didn't review any pretrial briefs from the ESI-Schering litigation, did you?

A. Yes, I did.

Q. Pretrial briefs?

A. Pretrial briefs, yes.

Q. And were those briefs prepared by both parties?

A. I read the pretrial brief of ESI.

Q. Do you know why you didn't read a pretrial brief by Schering?

A. It wasn't in the multiple number of banker's boxes that were provided to me. Frankly, I had plenty of arguments on one -- both sides of the case, so not having one brief or another probably wouldn't have affected the outcome of my analysis, but I did review carefully ESI's pretrial brief.

Q. So, is it possible --

A. That's what it was called. I assume that's what it was.

Q. You didn't review any witness lists, any trial witness lists, did you?

A. No.

Q. And you didn't review any exhibit lists, did you?

A. In the ESI case?

Q. Excuse me, thank you, for the Schering-ESI case, that's right.

A. Trial -- trial lists or deposition lists?

Q. Any exhibit lists prepared for the trial in the ESI-Schering case.

A. No.

MS. MICHEL: All right, nothing further.

MR. LAVELLE: Nothing further, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Miller. You're excused.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Let's take about an hour recess for lunch. We'll reconvene at 2:15.

(Whereupon, at 1:15 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:15 p.m.)

JUDGE CHAPPELL: Schering-Plough, are you ready to call your next witness?

MS. SHORES: We are, Your Honor.

JUDGE CHAPPELL: Proceed.

MS. SHORES: Schering calls Ray Russo.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

RAYMOND RUSSO

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name for the record, please.

THE WITNESS: Raymond Russo.

DIRECT EXAMINATION

BY MS. SHORES:

Q. Good afternoon, Mr. Russo.

A. Good afternoon.

Q. Mr. Russo, where do you live?

A. I live on 857 Bradford Avenue in Westfield, New Jersey.

Q. And what is your educational background starting with college, sir?

A. Undergraduate, I attended Rutgers University,

have a degree in economics. I have a graduate degree, MBA, in accounting from Rutgers. And I'm a CPA in the State of New Jersey.

Q. And how are you employed?

A. I currently work for Schering-Plough Corporation.

Q. And what is your position at Schering-Plough?

A. I'm the senior director of cardiovascular marketing for Schering-Plough Corporation.

Q. How long have you served in that capacity?

A. As a senior director of marketing, I've been in marketing for a little over six years.

Q. And how long have you been employed by Schering-Plough?

A. Almost 20 years.

Q. And can you just take us through the various positions that you've held over the past 20 years?

A. Sure. In the first half of my career, for the first ten years, I had various positions within finance, including international audits, corporate finance, financial analysts, marketing finance and primarily traveled my career through the finance area.

I moved over into marketing in managed care after about ten years, and I was the director of contracts and pricing for approximately two years, and

the last six years I've been in marketing.

Q. What are your duties and responsibilities as senior director for sales and marketing for cardiovascular products?

A. For in-line products we establish the strategic direction, we identify key issues, including our tactical plans and marketing plans. We have responsibility for establishing those plans. We do sales forecasting. We do market assessments. We also are responsible within our therapy area for business development and in-licensing responsibilities. So, it's kind of standard marketing stuff, but primarily strategic direction for the cardiovascular therapy area.

Q. What specific products do you currently have marketing responsibility for?

A. Currently I have marketing responsibility for a product called Integrelin. It's a GP2B3A inhibitor. It's used for acute coronary syndrome.

I also recently attained responsibility for a product called Zetia. It's ezetimibe. It's a cholesterol absorption inhibitor. And I also have responsibility for the unpromoted products K-Dur, Nitro-Dur, Normodyne and -- K-Dur, Nitro-Dur, Normodyne and Imdur.

Q. And how long have you responsibility over K-Dur?

A. I just recently got it back within the last six months, but in the beginning of my marketing career, I had K-Dur responsibility back in the mid-nineties.

Q. And to whom did you report in the mid-1990s?

A. I reported to Marty Driscoll, vice president of sales and marketing for Key Pharmaceuticals.

Q. Mr. Russo, what is K-Dur?

A. K-Dur is potassium chloride.

Q. And what is it used to treat?

A. It's used to treat primarily potassium depletion in coronary artery disease patients. These patients often are given products that are diuretics, and they are, quote unquote, nonpotassium stearates, so they are a potassium supplement to get these people's potassium levels in balance.

Q. How many dosage strengths does K-Dur come in?

A. It comes in K-Dur 10 mEq and K-Dur 20 mEq.

Q. What market does K-Dur compete in?

A. The potassium chloride supplement market.

Q. Is that sometimes referred to loosely at Schering as the potassium market?

A. Yes, um-hum.

Q. If you could open your booklet there, I've

given you a binder, to CX 17, please.

Sir, do you recognize CX 17?

A. Yes.

Q. And what is it, sir?

A. This is a marketing backgrounder. It's provided each year by the marketing research department. It's given to the product management team in anticipation of their preparation of their marketing plan.

Q. If you could turn to the second page of that document, you should have it in front of you and on your nifty screen there. It says there in the first sentence under the heading Market Overview, "K-DUR competes in a crowded $264 million potassium market which continues to grow in overall dollar sales with an 8% increase in 1995 over 1994."

How would -- well, let's first go back to the first page of this document. What is the date of this document?

A. The date is July 1st, 1996.

Q. And how would you describe the -- how would you characterize the level of competition in the potassium chloride supplement market in 1996?

A. It was intense. It was a very crowded market. I called it an undifferentiated market, but it's a very

crowded, competitive market.

Q. What do you mean by "undifferentiated"?

A. Well, this is potassium supplements, and potassium supplements basically are found -- you know, you can find potassium in food, you can find it in fruits and vegetables. This is a relatively simple compound that even can be purchased at health food stores. So, it's hard to differentiate your product within this marketplace.

Q. And was the potassium supplement -- I'm sorry, potassium chloride supplement market crowded and competitive in 1997 and 1998 as well?

A. Yes.

Q. How many potassium chloride products were there in the market at that time, do you recall?

A. A lot. My recollection, there were greater than 15.

Q. And if you could turn to the page of CX 17 that is marked on the bottom in the right-hand corner SP 003951, do you have that page, sir?

A. I do.

Q. There are some products listed on the left-hand column. Is that correct?

A. Yes.

Q. Are the products there potassium chloride

products that competed with K-Dur at the time?

A. They are.

Q. Now, over on the table on the left there, sir, I've put a number of pharmaceutical products -- the actual physical table as opposed to the one on the page. Can you identify what those are just generally, sir?

A. Yes, those are potassium chloride supplements.

Q. And just for the record, they bear exhibit numbers for identification purposes only of SPX 2209 to 2231.

Mr. Russo, how many potassium chloride supplements are on the table to your left, sir?

A. Oh, boy, there are about 15.

Q. And the two --

A. More than 15.

Q. Would you mind counting them up just so the record's clear?

A. Sure. I see 23.

Q. The first two right there on that corner, they should bear the exhibit numbers SPX 2209 and SPX 2210, do you see those?

A. Yes.

Q. And what are those?

A. Those are K-Dur, K-Dur 10 and K-Dur 20.

Q. What is the difference between K-Dur 10 and K-Dur 20?

A. It's basically the amount of potassium within the tablet.

Q. And are some of those products generic products?

A. Yes.

Q. Do all of the products on the table to your left, do they all compete in the same market?

A. Generally speaking, yes. Sometimes we'll differentiate from the liquids, but by and large, the potassium supplement market are the products -- all of these compete in that marketplace, yes.

Q. And sir, what therapeutic differences are there, if any, among these 23 or so potassium chloride supplements?

A. There are none.

Q. Mr. Russo, what involvement did you have in the pricing of K-Dur?

A. I'm responsible for recommending price increases. I was not on the product when the brand was originally launched, so I didn't establish the initial pricing, but I was responsible for price increases, I was responsible for a recommendation for contract pricing to managed care organizations, and future

pricing strategies.

Q. What effect, if any, did the existence of these 20-odd competitors to K-Dur have on K-Dur's pricing?

A. Well, it had a depressing effect. I mean, we could not -- we had to price these at a level that was competitive with the generic products. So, it didn't allow for a premium price, if you will.

Q. Why was that?

A. Because this is -- as I had mentioned, potassium supplements are fairly easy and very available products. So, there are many competitive low-priced entries in that marketplace.

Q. Now, if you could turn in your binder, sir, to the document marked CX 18, do you have that, sir?

A. I do.

Q. What is CX 18, sir?

A. CX 18 is the 1997 K-Dur marketing plan.

Q. Were marketing plans prepared for K-Dur from time to time at Schering?

A. Yes.

Q. And what is the date of this marketing plan?

A. September 10th, 1996.

Q. And can you turn to the page in that marketing plan marked at the bottom with 00041. Do you have that page, sir?

A. I do.
Q. Do you see a pie chart on that page?
A. Yes.
Q. What is that pie chart?
A. The pie chart represents the total prescriptions available in the potassium chloride supplement market year to date through April of 1996.
Q. What market does that pie chart represent?
A. That's the potassium chloride supplement market.
Q. Is there a market share reflected in that pie chart for K-Dur?
A. Yes.
Q. And what is that?
A. Thirty-seven percent.
Q. When Schering calculates K-Dur's market share, what market does it use?
A. It uses the potassium chloride supplement market, primarily the tablet market.
Q. And how much of -- if you were to take a slightly broader market of potassium chloride supplements to include the other potassium chloride supplements, what percentage of that market consists of potassium chloride supplements that are not tablets?
A. Oh, it's a relatively small amount. I believe

it's about 20 percent.

Q. Now, in the 1996 to 1998 time frame, what was K-Dur's market share in the market for tablets?

A. It was approximately 37 to 39 percent during that time frame.

Q. And what was K-Dur's market share in the market for potassium chloride supplements?

A. I'm sorry, it's approximately that amount, 37 percent.

Q. And is that, sir, that 37 percent, is that for K-Dur 10 or K-Dur 20 or both?

A. Oh, it's for both.

Q. How did K-Dur obtain that market share?

A. I think it was good marketing, but frankly, a lot of it has to do with -- these are relatively I think promotional-sensitive markets. So, we invested very heavily in a couple of things. We invested heavily in field force effort, so we edged our field base representatives on understanding the potassium chloride market so they could educate physicians. We branded our product. We wanted brand loyalty and name identification so physicians would write for our product specifically. And we had a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed

K-Dur and -- K-Dur 10 and K-Dur 20.

Q. You made a reference to field force. What is a field force?

A. I'm sorry, those are sales representatives that are employed by Schering-Plough that provide information to physicians regarding therapy areas and products.

Q. If you could turn in your binder now to the exhibit marked CX 20, do you have that, sir?

A. I do.

Q. What is CX 20?

A. CX 20 is the 1998 K-Dur marketing plan.

Q. And what is the date on CX 20?

A. August 1st, 1997.

Q. If you could turn to page 5 on that document, which is marked SP 004034, please, do you have that?

A. I do.

Q. I'd like to focus your attention on the paragraph under the heading Sales. Do you see that, sir?

A. I do.

Q. It says there, "The Potassium Chloride Market continued to grow in both dollars and prescriptions in 1996."

Is that true?

A. Yes.

Q. It says also that, "In 1996, the major products driving this increase in the Potassium Chloride Market were K-DUR (10 and 20 mEq tablets), the generic KCLs, and Klor Con (8 and 10 mEq tablets)."

Do you see that, sir?

A. Yes.

Q. Is that true?

A. Yes.

Q. And by "generic KCls," what do you understand that to mean?

A. That's generic potassium supplements, generic tablets.

Q. If you could turn to the next page of this exhibit, there's a reference in the paragraph under the pie chart there to, "our major competitors, Klor Con and generic KCL."

Do you see that?

A. Yes.

Q. Who were K-Dur's major competitors in this time frame?

A. Well, during that time period, it was Klor Con and the generic potassium supplements. There were some other smaller competitors, but those were the big ones.

Q. And why do you consider generics to be -- why

did you consider generics to be major competitors to K-Dur?

A. Well, because this marketplace, again, is simple potassium supplementation. If we weren't sure that a prescription was written for K-Dur or K-Dur 20, there was a real possibility that it could be switched to a generic potassium supplement, and so as that -- as the population aged and more patients became available to that marketplace to get treated by these products, often times the prescription would be filled not with a branded product but would be filled with a generic potassium supplement if it wasn't specified otherwise.

Q. How did Schering go about marketing K-Dur during this time frame?

A. Well, we spent a lot of time educating physicians about the need for potassium supplementation. We tried to brand, you know, our name and our image. We tried to be associated with good patient care. We tried to educate our field force regarding optimum potassium supplementation. So, we thought that as a result, people would remember our name and then prescribe our product.

Q. Does the fact that K-Dur 20 comes in a 20 milliequivalent tablet give it a therapeutic advantage?

A. No, not a therapeutic advantage.

Q. And does the fact that K-Dur 20 comes in a 20 milliequivalent tablet give it a marketing advantage?

A. Well, a little bit. I mean, it gives us something to differentiate it from. It's a larger tablet. There's more concentrated product. So, we tried to make something out of that, yes.

Q. Are there any marketing disadvantages to the fact that K-Dur 20 comes in a 20 milliequivalent pill?

A. There's one -- there is a marketing disadvantage, and that's the size of the tablet.

Q. And why is the size a disadvantage?

A. We used to kid, we used to call it a horse pill. I don't know if you have it here, but it's a fairly large tablet, and it's -- it's often the largest tablet these elderly patients take. So, we sometimes have a real challenge getting around that size when we promoted it to physicians and they had to, you know, educate their patients.

Q. So, for the record, I'm holding up a K-Dur 20. Does this look recognizable to you?

A. It looks about the size, that's it.

Q. And there's a line here down the middle of the pill. What purpose does that line serve?

A. That's called a scoring, and many tablets have that. You use that so that you can break the tablet in

half.

Q. Why would someone want to break the tablet in half?

A. It makes it easier to swallow, makes it easier to mix in liquid, simpler to take basically.

Q. How much potassium chloride does a physician typically prescribe in terms of how much of it a patient has to take in one day?

A. Yeah, I mean, generally speaking, generally, a physician will prescribe approximately 40 mEqs of potassium per day. That's on average, depending on the disease and the level of potassium that they observe, but that's approximately the amount.

Q. And if a patient had been prescribed 40 milliequivalents of potassium, would the prescription typically require the patient to take that all at once?

A. Well, it generally would -- because of the size of the tablet and the patterns that these elderly CAD patients take these drugs, often times they will tell them to take them with meals, so it will likely be once in the morning and once in the evening, so twice a day.

Q. And you made a reference there to CAD patients. Who are those?

A. I'm sorry, coronary artery disease, heart patients.

Q. Thank you.

Now, if the prescription was for 40 milliequivalent but it was written for a 10 milliequivalent product, how many tablets would that mean a patient had to take a day?

A. They would have to take four tablets of 10 mEq a day.

Q. And again, would such a prescription typically require the patient to take the four pills all at once?

A. That's a lot of potassium. They will generally split it out two 10s in the morning and two 10s in the evening likely.

Q. And again, if the prescription had been written for 40 milliequivalents but the prescription was for K-Dur 20, how many pills would that require the patient to take?

A. Two.

Q. And how many times a day would the patient have to take that?

A. I mean, generally speaking, again, it would be one tablet in the morning and once in the evening. So, twice a day, one tablet twice a day.

Q. If we could go back to CX 18 and turn to page 28, I believe it's the last page of that document. Do you see there's a heading call Promotional Budget

there, sir?

A. Yes.

Q. The first sentence underneath that heading says, "Achieving our goal of $200 million in sales for 1997 will require increased market penetration and market expansion activities."

Do you see that?

A. Yes.

Q. It then it says, there's a line underneath some bullet points that says, "Total promotional dollars needed for 1997," and then there's a figure, $9 and a half million.

Do you see that?

A. Yes.

Q. Did Schering spend approximately $9 and a half million in promotional dollars in 1997?

A. That was our approximate spend, yes.

Q. Does that figure capture all of Schering's expenditures for the promotion of K-Dur in that year?

A. No, it only pertains to the marketing budget. In addition, we would have spent on field force resources, so a large portion of our field team would have been promoting K-Dur, and those -- and the costs associated with that team would have been applied to the drug.

Q. Approximately how much money did Schering spend on its field force activities in this time frame?

A. For K-Dur?

Q. Yes.

A. My -- I estimate about $10 million. That would be approximate. I'd have to recall where their positioning in the call cycle was, but approximately $10 million.

Q. So, that $10 million, would that be on top of the $9 and a half million that's represented here?

A. Yes.

Q. Now, how does that figure compare with what Schering's competitors spent on promotion and marketing of their potassium chloride products during this time frame?

A. We were by far the market leader in spending levels certainly and in prescriptions.

Q. Now, how does the price of K-Dur 20 during this time frame compare with the price of other potassium chloride supplements?

A. It's a -- it's approximately the same. It depends on the managed care contract, but it's fairly similar.

Q. As part of your responsibilities as senior director of marketing and sales for cardiovascular

products, and now I'm focusing on the mid-nineties time frame that you referred to earlier, did you have sales forecasts prepared?

A. Yes.

Q. Why did you have sales forecasts prepared?

A. It's a standard practice when you're preparing your strategic plan to basically understand trends in the marketplace, performance of your product and assess profitability of your product. So, it's a standard practice.

Q. Would they sometimes contain different scenarios?

A. Yes.

Q. Why was that?

A. Well, you're trying to anticipate contingencies, that would be new entrants into the marketplaces, new therapies that might obsolete your product, new changes in the market that might impact both positively and negatively how you were able to sell and promote your product.

Q. Going back to some of the potassium chloride supplements that are on the table to your left, are some of those branded products?

A. Let's see, yes, that looks like a brand. Yes.

Q. And going back again to sales forecasts, was it

your practice to regularly review such forecasts for the products that you had responsibility for?

A. Yes.

Q. Did the sales forecasts that you reviewed, did they sometimes contain assumptions about the entry of generic products?

A. They did.

Q. What were those assumptions generally based on?

A. Well, we try to obtain third-party information. Our market research department reviews either press releases or SEC filings or basically industry information that basically -- that basically will identify types of products that are, quote unquote, "in development," you know, vis-a-vis some of the generic manufacturers.

Q. Was it customary for the people who prepared these sales forecasts to be in contact with Schering's legal department about the status of various patent litigations?

A. No.

Q. Do you ever recall that being done?

A. No.

Q. Okay, if you could turn in your binder there to CX 682, do you have that document, sir?

A. I do.

Q. What is CX 682?

A. This is a risk authorization form. It's seeking approval to purchase and print packaging materials for a Warrick potassium chloride supplement.

Q. And can you tell what the date is of this document?

A. It looks like it's March 2nd, 1997.

Q. And does this reflect an approved expenditure for packaging materials?

A. Yes, it's a request for -- yes.

Q. Why were you authorizing -- I'm sorry, and your name is there as authorizing this expenditure. Is that right?

A. Yes.

Q. Why were you authorizing an expenditure of $93,000 to purchase packaging supplies?

A. Well, this is just packaging supplies. I mean, this is a risk authorization. We had a division at Schering that actually would launch first mover generics if, in fact, there was another generic competitor that got potentially approved, and what this was doing was manufacturing the purchase of packaging materials, which often had a fairly long lead time.

Q. And what was the name of Schering's generic division?

A. That was Warrick Pharmaceuticals.

Q. What does this document reflect about Schering's beliefs about the likelihood of generic entry at this particular point in time?

A. I mean, it basically is preparing us. It doesn't anticipate imminent approval, but it's preparing us in the case of an approval. So, it doesn't, you know, assume that it's going to -- that's why it's a risk authorization. If they knew it was going to be approved, it wouldn't require, you know, risk authorization.

Q. If Warrick was intending to go about manufacturing an actual generic version of K-Dur, would there be another risk authorization form like this for the manufacture of the product?

A. Likely.

Q. And do you recall whether that was done in this time frame?

A. I don't.

Q. Were there other occasions on which Schering prepared risk authorization expenditures like this or approved expenditures such as this?

A. Yeah -- yes. I -- in my portfolio, there were a number of products that were under the threat of potential generics, and occasionally we would -- we

would recommend and approve packaging materials for those products.

Q. And what happened in those other instances when you approved risk authorization expenditures?

A. Well, sometimes -- sometimes we would use them, and -- when the product was approved, and sometimes we would have to D&O, that would be destroy and obsolete them, so...

Q. And why did you destroy and obsolete them?

A. We felt that there -- you know, there was no pending generic coming, so we destroyed the materials.

Q. So, sometimes you had authorized expenditures such as this and it turned out that the authorization was unnecessary. Is that right?

A. That's correct.

Q. Now, you said earlier that among your responsibilities was the duty to evaluate in-licenses. Is that correct?

A. Yes.

Q. What does Schering normally do when it evaluates in-licenses?

A. Well, basically we'll look at the nature of the product. We'll determine its market potential. We'll determine its fit within our current portfolio. We'll determine if there's a level of investment we can make

to make this product even larger than maybe the owner of the license, you know, can do. We'll do some sales forecasting. We'll do some market forecasting. And we'll do basically a financial analysis to see if this is a viable option.

Q. And what does Schering normally do in terms of due diligence to evaluate whether to proceed with the opportunity?

A. I mean, that depends. I mean, it depends on the nature of the opportunity. If it's an early stage product which is early in development and it's a new and novel compound, we will do a lot. If it's a late stage compound that has, you know, a characterized profile, it has phase III data, clinical data available, and it has a filed NDA, for example, we'll do much less.

Q. What relationship is there, if any, between the intensity of Schering's due diligence or evaluation process and the risk involved to Schering with the particular product?

A. Well, certainly the higher the risk, the earlier the development, the more involved the, quote unquote, "due diligence" or review process would be.

Q. Is there any standard approach that Schering utilizes for purposes of due diligence?

A. Not that I know of.

Q. What relationship is there, if any, between the stage of a development of a particular product that Schering is evaluating and a risk to Schering in doing a deal?

A. Well, the later the stage the product, the higher the opportunity to do the deal in my mind. I mean, you know more about the drug, it's familiar, sometimes it's on the marketplace. So, there's a higher opportunity for a deal to occur the closer it is to market.

Q. And what do you mean by "higher opportunity"?

A. More likelihood that you'll strike a deal with the licensee, the license holder.

Q. Is there more or less risk involved to Schering in doing a deal for a late stage product as compared with an early stage product?

A. My belief is there's less risk, and --

Q. Less risk with a later stage product?

A. Oh, I'm sorry, less -- certainly less risk with a later stage product. There is more that is known about it. You can understand it better. You can even sometimes understand how the market will receive it. So, there's less risk with a later stage product.

Q. Did there come a time when Schering became

interested in a sustained release niacin product?

A. Yes.

Q. What product was that?

A. The product that I was familiar with was a product called Niaspan from Kos Pharmaceuticals.

Q. When do you recall Schering being interested in that product?

A. In 1996.

Q. If you could turn to CX 575 in your binder there, sir, do you recognize that document?

A. I do.

Q. What is it?

A. It is a CV business development subcommittee meeting minute document.

Q. And what's the date on it?

A. May 27th, 1996.

Q. If you could turn to the second page of that document, there's a reference there to Kos' Niaspan. Do you see that?

A. Yes.

Q. It says, "Marketing is still interested in this sustained release niacin product."

Do you see that?

A. Yes.

Q. That was true at the time?

A. Yes.

Q. It says, "Action: Mr. Russo."

Is that you?

A. Yes.

Q. Could you turn back to the first page of this document? Do you see there a reference to a drug called Lipidil?

A. Yes.

Q. What is that?

A. Lipidil is a fenofibrate -- it's fenofibrate. It is a fibrate product that's used for the management of dyslipidemias, primarily elevated triglycerides.

Q. And was Schering evaluating an opportunity linked to that product at this time?

A. Yes.

Q. Did Schering negotiate a deal for that product?

A. We did not.

Q. What ultimately happened to that product, if anything?

A. We stopped our negotiations with this French company. We just felt that we could not make a go of the product for a number of reasons, the way that that was -- that that was currently formulated.

Q. Did that product eventually find its way to the marketplace?

A. It did.

Q. What is it called today?

A. Tricor is the brand name. It's -- fenofibrate is its generic name.

Q. And again, why was Schering interested in fenofibrate?

A. Well, fenofibrate fit into a therapy area that we had a fairly -- a very significant development program ongoing in clinical research, and that would be the management of dyslipidemias or elevated lipids. So, it was a good strategic fit.

It was also a product that would likely be sold to a physician base that we currently called on, so it was a good fit for our field force. And, you know, I would call it a -- it was a bridge opportunity to get us from where our products were currently being less and less promoted to our future products which we expected in the year 2001 or 2002.

Q. And what future products were those?

A. Well, the biggest future product in there is a product that we characterize as SCH 58235, and it's ezetimibe.

Q. And what is ezetimibe used to treat?

A. Ezetimibe is a cholesterol absorption inhibitor. It works on the small intestine, the brush

border of the small intestine, and it reduces LDLs. It's a lipid management product.

Q. So, is it fair to call that a cholesterol drug?

A. Yes, um-hum.

Q. And fenofibrate, is it fair to call that a cholesterol drug?

A. Yes, yes.

Q. So, when you refer to hyperlipidemia, what is that?

A. Oh, it's the cholesterol management marketplace.

Q. Now, I think you said that this product is now known as Tricor. Is that correct?

A. Yes.

Q. How is it doing in the marketplace, do you know?

A. Fairly well. I think it's selling about $300 million a year.

Q. With the benefit of hindsight, do you wish that Schering had done a deal for Lipidil?

A. I do.

Q. All right. Going back to Niaspan, why was Schering interested in a sustained release niacin product?

A. Well, again, this is a -- this was an excellent

bridge product for our lipid management development program. So, niacin was a -- was a very well-characterized product that had certain properties that were unique. It elevated good cholesterol, and so if someone could get around some of the issues regarding Niaspan, this was a very nice product. It fit our product portfolio. We had some available outage in our -- in our field force. So, for both strategic and field force fit reasons, it was a good product for us.

Q. And you made a reference there to it being a good bridge product. Bridge to what?

A. Oh, I'm sorry. Bridge from, you know, our development program in ezetimibe to ultimate launch of ezetimibe, so we could learn that therapy area, understand the customers, get familiar with them, understand, you know, the disease state, and then when we launched our -- what I consider our blockbuster product, we would be well prepared.

Q. If you could turn to SPX 614 in your binder, do you have that, sir?

A. I do.

Q. This is a memorandum from somebody named Jim Audibert to Distribution dated March 10th, 1997. Is that correct?

A. Yes.

Q. Who is Jim Audibert?

A. Jim Audibert was my counterpart in global marketing. He was the senior director of global marketing for cardiovascular products and central nervous system products, and he and I worked together in marketing for Schering.

Q. And by your "counterpart," do you mean that Mr. Audibert had responsibility for selling cardiovascular -- for selling and marketing cardiovascular products overseas?

A. Yes, ex-U.S., and he was also responsible for consistency of strategies worldwide.

Q. Whereas you were responsible for the marketing of such products in the United States?

A. Only the United States, that's correct.

Q. It says here that -- let me zoom in -- "SCH 58235 has the potential to be one of the biggest products in the SPRI portfolio."

Do you see that?

A. Yes.

Q. And what is SCH 58235?

A. That's our cholesterol absorption inhibitor called ezetimibe.

Q. Do you know what the anticipated sales of

ezetimibe are currently?

A. Well, we have forecasts that go, you know, in the range of $6 billion, $7 billion approximately.

Q. Is that an annual sales figure?

A. Per annum, yes.

Q. And how close is ezetimibe to FDA approval?

A. We filed our NDA in December of 2001, and we hope for approval by the end of this year.

Q. If you go down farther in this document, it says here, "To accomplish this evaluation, the U.S. and global marketing groups have agreed to develop a global commercial assessment."

Do you see that, sir?

A. Yes.

Q. What did that relate to?

A. We were being asked to estimate the potential of this product worldwide and do some sales forecasting.

Q. And what did that project entail?

A. Basically assessing the marketplace, assessing this product's position within the marketplace, assuming some sort of pricing strategy, and then forecasting sales dollars.

Q. And did that involve an understanding of the worldwide cholesterol market?

A. Yes.

Q. How large was the cholesterol market at the time that Schering was looking at Niaspan?

A. Well, in the mid-nineties, it was my recollection that it was in the $5 to $7 billion range. It was a significant market.

Q. Now, going back to Schering's negotiations with Kos for Niaspan, how did Schering express its interest to Kos, do you know?

A. Well, we made a commercial contact to the company.

Q. And what do you mean by "commercial contact"?

A. I'm sorry, our market -- many of the folks at Kos had also worked at Schering. We were -- we knew each other. This is through affiliations. We knew each other in -- you know, through business relationships. So, we contacted them.

Q. Did Schering request any information about Niaspan from Kos?

A. Yes.

Q. And did there come a time that Schering received some information from Kos about Niaspan?

A. Yes.

Q. If you could turn to CX 540 in the booklet there, do you have that, sir?

A. I do.

Q. It's a memorandum dated February 11th, 1997 to Rudy Ress from Karin Gast. Is that right?

A. Yes.

Q. And you're copied on that?

A. I am.

Q. And what is this document, sir?

A. This is basically a memo from our business development manager identifying what material had been received from Kos regarding Niaspan.

Q. And what did that material consist of?

A. It included a Niaspan profile from their IPO, some proposed labeling, excluding an indications section. It gave some proposed labeling, a single page of proposed labeling indications which they believed were likely to be approved. And we got a reprint of their first clinical publication on Niaspan.

Q. There's a reference here to confidential disclosure. Had Schering entered into a confidentiality agreement with Kos?

A. Yes.

Q. Was Schering expecting to receive more information from Kos?

A. Yes, we had hoped to receive some more information.

Q. Had Kos by this time submitted a new drug application?

A. It was my understanding they had, earlier the previous year.

Q. What stage was Niaspan in?

A. I would consider it, you know, a phase III prelaunch product, late stage.

Q. If you could turn now to CX 543, do you have that?

A. I do.

Q. And what is CX 543?

A. It's a contact report from our business development group regarding a telephone call that myself and Jim Audibert had with the folks from Kos.

Q. And the date of it is March 13th, 1997. Is that right?

A. Yes.

Q. And again, who is Mr. Audibert?

A. Jim Audibert is the senior director of global marketing, and like I said, responsible for cardiovascular products ex-U.S. and global strategies.

Q. If I could focus your attention on the second paragraph, it says there that, "Jim in particular wanted to know what is the safety profile for Niaspan."

Do you see that?

A. Yes.

Q. What was Mr. Audibert's involvement in evaluating Niaspan?

A. Well, as I had said, Jim is responsible for overall global strategy and ex-U.S. strategy. This product had the potential to be a worldwide deal. So, Jim in his role was interested in, you know, the nature of the product.

Q. And why was he interested in Niaspan's safety profile?

A. Well, Jim -- Jim is a knowledgeable guy. I mean, he's a pharmacist. I think he has a Master's in pharmacology even. And, in fact -- so, he wanted to know a little bit about the profile of Niaspan just to assess it from a -- from a pharmacologic standpoint, because niacin, frankly, had a historic profile that had some safety concerns. So, I think Jim's particular interest there was to assess whether those safety concerns could be limited by this sustained release Niaspan. So, I think that was his particular interest.

I mean, Jim actually did this for a number of a therapy areas. He had been involved in asthma/allergy, dermatology, CNS and cardiovascular medicine. So, he was fairly knowledgeable about pharmalogic -- pharmacologic products.

Q. Going down farther in the document, there's an indication here that, "FDA has completed the medical review and they are currently discussing labeling with Kos."

Do you see that?

A. Yes.

Q. What is the significance of the FDA having completed the medical review?

A. Well, it generally means that most of their major issues are likely to be resolved, and now they're just negotiating finalized labeling prior to approval.

Q. Did there come a time when Mr. Audibert consulted with marketing people in Schering's overseas subsidiaries about their interest in a sustained release niacin product?

A. Yes.

Q. If you could turn to CX 544, do you have that?

A. I do.

Q. This is a memorandum dated March 14th, 1997 from Jim Audibert to Distribution. Do you recall seeing this document before?

A. I -- I did not see this document. I wasn't copied on this particular document.

Q. Let's go to the next page where we can see the distribution. There's some countries there and some

people, people's names underneath the countries. Do you know who those people are?

A. Yes, they're the marketing directors primarily in cardiovascular medicine for those various subsidiaries.

Q. And are these the people who would be responsible for selling Niaspan if Schering had gotten overseas rights to it?

A. Yes, they would be primarily responsible for the marketing of Niaspan ex-U.S.

Q. And again, I think you said you don't remember seeing this document, but you do recall that Mr. Audibert consulted with some folks in Schering's overseas outfits. Is that right?

A. Yes. Yes, Jim had told me he was going to contact the ex-U.S. subs and determine their interest for Niaspan.

MR. SILBER: Objection, Your Honor, hearsay. He's testifying to what Mr. Audibert stated.

MS. SHORES: Your Honor, I think this witness is perfectly capable of testifying as to what he understood Mr. Audibert was doing.

MR. SILBER: Your Honor, I believe Mr. Audibert's going to be called as a witness. Mr. Audibert can testify as to what he stated.

MS. SHORES: Your Honor, both of these people have been -- they had the opportunity to have taken their depositions on these subjects. There's really no debate about what either of them is going to say about this issue.

JUDGE CHAPPELL: The biggest problem you have is the answer is not responsive to the question. You can restate the question or have the court reporter read it back, but I am going to sustain the objection, not on hearsay, but because it wasn't responsive.

BY MS. SHORES:

Q. What responses do you recall Mr. Audibert getting from these overseas marketing people?

A. I understood that Jim had gotten a number of responses from the overseas subs and that a number of them were very favorable in the response and a number of them were less than favorable in the response.

Q. Did Schering do any market research in connection with its evaluation of Niaspan?

A. Yes.

Q. If you could turn to CX 576, do you have that, sir?

A. I do.

Q. And what is CX 576?

A. This is a market research assessment done by a

third party regarding Niaspan.

Q. Did Schering have to pay for this market research?

A. Yes.

Q. Approximately how much did Schering have to pay?

A. Generally these types of evaluations cost anywhere from $20,000 to $30,000.

Q. And what does that signify, if anything, about the level of Schering's interest in Niaspan?

A. It demonstrates we were very serious about this product.

Q. Did Schering consult with any other third parties in connection with its evaluation of Niaspan?

A. Yes, we actually had a Lipid Advisory Panel meeting that not only discussed Niaspan but discussed our development program in cholesterol management, and we discussed that product with them.

In addition, we have consulting arrangements with thought leaders in the area of cardiovascular disease, and we discussed the product with them.

Q. Who are the members of this Lipid Advisory Committee?

A. I don't --

Q. I'm not asking for specific names.

A. I don't recall them all, but Dr. Vogel, Dr. Hunninghake, I believe Dr. Gotto. These were some of the leading lipid manager -- you know, thought leaders in this area of treatment.

Q. Did you participate in any negotiations with Kos?

A. I did.

Q. What sort of arrangement was being discussed with Kos?

A. We understood that Kos was seeking to have a co-promotion arrangement.

Q. What is a co-promotion arrangement?

A. A co-promotion arrangement generally means that both parties would be involved in the sales and marketing of the product under one brand name. So, generally they would split the effort that was done in the field force, and they would split the cost of the marketing.

Q. How does a co-promotion arrangement differ from an in-license?

A. Well, a strict in-license means that you would retain all control and all rights over the product. So, you'd be responsible for all of the expenditures, all of the investment, all of the strategic direction, and you basically would not have a partner. You'd

maintain control of the product.

Q. Do you recall specifically what Kos -- what terms Kos was seeking as part of a co-promotion arrangement?

A. I recall some of the specifics on the co-promotion arrangement. They were seeking to retain marketing control. They were seeking to establish themselves with a field force. They were seeking to invest I believe it was up to 50 percent of the promotional effort. And they were seeking to split the resulting profit from the effort.

Q. Was Kos seeking anything with respect to a level of call activity?

A. Yes. They wanted a very specific level of primary detail, what we call, and primary detail means that this product would have to be the first product that a rep would present to a physician. And in our way of thinking, that's a very valuable -- a valuable commodity.

Q. What was Schering's reaction to the request for primary positioning?

A. Frankly, that's very -- that would have been very difficult in this kind of co-promotion arrangement where we were sharing the profits.

Q. Why is that?

A. We had other products that frank -- that were our own product in which we would receive all of the profit that we would rather have used that primary detail on. So, the level of primary detail that they were requesting just was not in sync with our available outage.

Q. Was Kos seeking guarantees with respect to the level of call activity?

A. Yes. They wanted specific numbers of specific types of calls through the launch period.

Q. And what was Schering's reaction to that?

A. We felt we couldn't accommodate that level of call activity and that type of call for them.

Q. Did you participate in any face-to-face meetings with the people from Kos?

A. Yes.

Q. And where was -- where was that meeting or where were those meetings?

A. The one meeting I participated face to face with Kos was in Miami at the Kos corporate headquarters.

Q. Who else attended, if anyone, on behalf of Schering?

A. It was myself, it was my product manager, David Grewcock, it was our manager of marketing research,

Toni DeMola, and it was our business development director, Karin Gast.

Q. And who participated, if anyone, on behalf of Kos?

A. My recollection was that Dan Bell, their COO participated; David Heatherman, their vice president of sales and marketing. They also had a project manager for Niaspan, and I can't recall his name, and they had a business development representative.

Q. If you could turn to SPX 112 in your binder, please, do you have that, sir?

A. I do.

Q. There are some names there listed for Kos. Do those names refresh your recollection as to the name of the product manager?

A. Yes.

Q. Who was that?

A. Well, their product director was a gentleman named John Kalimtsis.

Q. I would like for you now to turn to the pages of this exhibit marked SP 002750, that's on the bottom right-hand -- 2750. Do you see that?

A. I do.

Q. And just leafing through the rest of that exhibit all the way to the end, do you recognize those

pages?

A. Yes.

Q. And what are these?

A. This is -- this is the presentation we made to Kos during that meeting.

Q. So, are these copies of overheads that were used at this --

A. Yes, these were overheads that we used during the presentation with Kos regarding Niaspan.

Q. If you could turn to 2752, do you see that?

A. I do.

Q. It says there, "Strategic Fit Within CV Franchise - Long Term Commitment to Lipid Reduction."

What is that a reference to?

A. Well, we were trying to demonstrate to Kos that we had a long-term commitment to this therapy area, that we were going to take it very seriously. We had products in our pipeline that were coming that were a natural fit. So, this was going to be an important element of, you know, of our franchise, of our CV franchise, short term and long term.

Q. Was ezetimibe one of the products in the pipeline?

A. Yes, that was the primary product.

Q. And if you could turn to 2754, it's two more

pages in, do you have that?

A. I do.

Q. It says there, "Open Issues," and there's a number of things listed there.

A. Yes.

Q. One of them is global option. Do you see that?

A. Yes.

Q. What is that a reference to?

A. We had some early discussions about this being potentially a worldwide deal. So, although I was focusing on the U.S. opportunity, we didn't want to overlook an opportunity that was ex-U.S. so, we still were in the early phase of discussion regarding a global option.

Q. Now, what happened at the meeting in Miami?

A. Well, I recall that we did a very successful job in convincing the Kos folks that we would make a good partner. We had a cogent story. We demonstrated we knew the marketplace. We presented them with issues that we felt we could most uniquely and effectively address. We presented them with access to a field force that we thought was tops in the industry, particularly in this therapy area, cardiovascular medicine. So, my take-away was that we had a very good and successful meeting.

Q. And what happened next?

A. We committed to follow up with the folks from Kos, and we would begin the process of putting together broad-based deal terms.

Q. Did part of that process involve the preparation of sales forecasts?

A. Yes. We were going to go back, internally assess the value of the product to Schering-Plough, do a number of sales forecasts under a number of scenarios, and then from that establish broad-based deal terms which we would ultimately present to Kos.

Q. If you could turn to the exhibit marked CX 550 in your binder, I'm going to put it on this thing just briefly, but I have a better copy of it in here.

Is Exhibit CX 550 some of the sales forecasts that Schering prepared?

A. Yeah, I had SP 2743 -- is that where --

Q. Yes, SP 2743.

A. Yes, yes.

Q. And if you could look on the next page and the page after that, I believe there's some more forecasts.

A. Yes.

Q. What are the differences between these -- I count -- well, there are three spreadsheets here. What are the basic differences among them?

A. Well, the first forecast is -- it's called Ray's Forecast - Base. This is my assessment as to the base case potential for Niaspan, and in this base case, I did a market assessment, I applied some overall estimates of market penetration and market growth, and then I applied two pricing scenarios to that product. So, this was -- this is, in my view, the base case forecast for the potential of the Niaspan product.

The second one is Toni's forecast, and that's SP 002744, and that's, in effect, a downside estimate. That would be what we felt might have been the lowest potential of the product. It was done by marketing research, who tend to be a little more conservative in these things, but this was Toni DeMola, our manager of marketing research, this was her estimate of the downside forecast.

And the third estimate is my upside forecast. What this demonstrates is what I thought might be the upside potential for the product, assuming we would get early, more aggressive market penetration and higher market share. So, this is basically three sensitivity analyses around the potential of the product.

Q. And which of these forecasts did you think was most realistic?

A. I thought the base case was.

Q. And that's at 2743. Is that right?

A. Yes.

Q. Do you see there on your screen, is that a -- what I've tried to do is present to you a slightly more legible copy of your base case. Does that appear to be what this is?

A. Yes.

Q. And again, you can either look on this one or the one in front of you, but are there two different price scenarios in this spreadsheet?

A. Yes.

Q. And why are there two different price scenarios?

A. Well, we used two pricing assumptions. One was based on an existing product on the market, a niacin sustained release product, which had a very low price, and then we also priced it compared to I would call it a somewhat like product called gemfibrozil, but it was a generic gemfibrozil. So, we felt if this product could deliver on the product profile that they assumed, the price that we could achieve would be closer to that higher price based on generic gemfibrozil versus the current pricing of a product that was not widely used.

Q. And again, if you could just take us through this spreadsheet and explain how you prepared it.

A. Sure. We start with the overall U.S. population and we estimate through third-party data the percentage of patients that are likely to be managed with a prescription for lipid disorders. We look at the total eligible patient population. We know approximately how many of those patients are likely to receive a prescription of any kind, and we assess what we think we can do vis-a-vis the niacin market.

We also currently know the number of patients that are currently receiving a niacin prescription, so based on that information and based on our awareness of the product profile, we make some estimates as to what we believe we can do with adequate levels of sales and promotion to expand that market and take a more significant market share from the existing products and other like therapies within that marketplace.

Q. Now, going again to your price scenarios, did you have a view as to which of these would be more realistic?

A. I thought the generic gemfibrozil price was the most reasonable one.

Q. How did the price of generic gemfibrozil compare with the price of other cholesterol-lowering drugs, such as statins, do you recall?

A. Well, statins were just being, you know,

launched and having their heyday during that time, and that was significantly less. Gemfibrozil was significantly less.

Q. And how did you estimate the share assumptions in this forecast?

A. I mean, part of it is our experience in growing markets, our experience in developing markets. We felt with the amount of effort we would put forward, our expertise in sales and marketing, we felt we could -- we could achieve those market share and market penetration assumptions. So, it's based on past experience and awareness of the marketplace.

Q. So, as I understand it, your base case was what you thought was the most realistic scenario?

A. Yes.

Q. Was that the most optimistic of the forecasts that you did?

A. No, no.

Q. And as I understand it from your testimony, it's the base case with price scenario II that you thought was the most realistic. Is that right?

A. Yes, that's correct.

Q. Did this -- did this forecast reflect your best business judgment at the time?

A. It did.

Q. It was your best estimate of what you thought Schering could achieve?

A. Yes, it was.

Q. Was it connected in any way to any patent litigation?

A. No.

Q. Were the negotiations with Kos, were they arm's length negotiations?

A. Yes.

MR. SILBER: Objection, Your Honor, leading.

MS. SHORES: I'll withdraw it if you would like, Your Honor.

JUDGE CHAPPELL: Restate the question, please. I'll sustain the objection.

BY MS. SHORES:

Q. How would you characterize the negotiations between Schering and Kos?

A. They were independent negotiations that we carried on in the normal course of business.

Q. Now, again, focusing on what's on the screen before you, that's a page from CX 550, there's some sales figures highlighted across from the reference to price scenario II. Do you see that?

A. Yes.

Q. And they reflect the amount of sales that you

anticipated Schering could achieve. Is that right?

A. Yes.

Q. At the time, did you think that Schering could achieve these sales if Schering had gone forward with the co-promotion arrangement?

A. Yes.

Q. And what is the amount of sales that you were projecting Schering could achieve in the year let's say 2000?

A. Approximately $109 million.

Q. Okay, I'd like you to turn now to CX 554 in your binder. I'm sorry, I meant to say CX 551. Do you have that, sir?

A. I do.

Q. What is CX 551?

A. It's a financial analysis regarding Niaspan. It's basically a net present value analysis that takes a product profit and loss statement, estimates a profit after tax, generates a cash flow from that, and then discounts that cash flow to arrive at a net present value.

Q. And you might have just told me this, but how do you go about preparing a document like CX 551?

A. Well, the critical issue is you get the sales right. So, you take your sales forecast, and then you

put in trailer costs. So, for example, you'll include your cost of goods, the cost to manufacture your product, then you'll include additional costs such as marketing costs for promotion, for field selling, if there are any royalties expected, if there are any cash discounts you anticipate, so you include all of those trailer costs into the P&L statement.

You apply your estimated corporate tax rate to achieve a profit after tax, and then you make some assumptions regarding inventory levels, and you come up with a cash flow -- with a cash flow stream, and you take that cash flow stream and you discount it to the present based on usually internal hurdle rates, and I believe 13 percent is the rate we used here, and you come up with a net present value of the overall -- you know, of the overall value of this product.

Q. I'm going to show you now on your screen there a highlighted version of CX 551. Can you see that at all?

A. Yes.

Q. Okay. What I've tried to do there is to highlight -- and you can look at the one in your binder if it's easier, but I've tried to highlight the sales figures on CX 551. Can you see that?

A. Yes.

Q. How do those sales figures relate to the sales forecasts that were contained in the previous exhibit, which was CX 550?

A. They're the same.

Q. And the first page of this document says, "RR - Base Scenario 2."

What is that a reference to?

A. This is a look at the base scenario using the gemfibrozil pricing.

Q. And RR, who is that?

A. I'm sorry, that's Ray Russo, that's me.

Q. Now, did there come a time when Schering made a proposal to Kos?

A. Yes.

Q. If you could turn to CX 554 in your binder, do you have that?

A. I do.

Q. What is CX 554?

A. This is a first draft of proposal terms that we submitted to Dave Heatherman, who was the vice president of sales and marketing for Kos.

MS. SHORES: Just one second, Your Honor.

(Counsel conferring.)

MS. SHORES: Your Honor, I'm admonished that this is an in camera document, so we will have to clear

the courtroom briefly, I'm afraid.

JUDGE CHAPPELL: Okay. Are there going to be a number of in camera-related questions?

MS. SHORES: No, there is not, no.

JUDGE CHAPPELL: Will there be any more reference to in camera in your direct examination?

MS. SHORES: I had intended to ask the witness some questions about this particular exhibit.

JUDGE CHAPPELL: But only this?

MS. SHORES: Only this one.

JUDGE CHAPPELL: Because where I was going was if we could do it all in one place in your direct exam if there was any more.

MS. SHORES: This is it, Your Honor.

JUDGE CHAPPELL: Okay, I am going to have to ask the public to leave the courtroom. We are getting ready to consider an in camera document which is excluded from the public's view. This testimony is not subject to public hearing. You will be notified when you can re-enter the courtroom. Thank you.

(The in camera testimony continued in Volume 14, Part 2, Pages 3588 through 3591, then resumed as follows.)

JUDGE CHAPPELL: I suppose that is your document, so you can handle it as you will.

MS. SHORES: It is. I'll get it --

JUDGE CHAPPELL: I'm more concerned about nonparties' documents.

You may proceed.

MS. SHORES: I really should have gotten the Schering version of that document, it would have helped. I'm sorry.

BY MS. SHORES:

Q. What was Kos' reaction to Schering's proposal?

A. It was not a favorable reaction. They felt that we did not offer them a fair proposal.

Q. Were you surprised by that?

A. I was surprised.

Q. Did they indicate what they wanted in addition to what Schering was offering?

A. They wanted significant guarantees regarding the level of promotion and the level of field force activity we were willing to commit, and they wanted significant additional payments, generally up-front and milestone payments. So, those were the two big issues.

Q. Do you recall how large an up-front payment Kos wanted?

A. I don't recall the exact amount, but I recall Dave Heatherman telling me that he wanted a

Lipitor-like deal, and I knew that the Lipitor deal had a very heavy early payment and very significant milestones.

Q. Now, did Schering make another proposal after Kos had that reaction to this proposal?

A. We did not.

Q. Why not?

A. It was very clear that we were not even close in negotiating terms. It had become a little bit contentious. We felt we could not bridge the gap, and we felt it wasn't worth our time to continue those negotiations.

Q. I'd like you to turn to CX 558 in your binder.

Actually, I will just withdraw that question, and no further questions, Your Honor.

JUDGE CHAPPELL: Cross?

MR. SILBER: Yes, Your Honor.

CROSS EXAMINATION

BY MR. SILBER:

Q. Hi, Mr. Russo, my name is Seth Silber. Good to meet you.

A. Hi, Seth.

Q. I just wanted to start by first asking you a couple of questions about K-Dur, and if we could look at CX 17 in your binder, do you have that in front of

you?

A. I do.

Q. Okay. If you could turn back to SP 003946, please, and at the top it says, "Future Competition."

Do you see that?

A. I do.

Q. Okay, the second paragraph says, "Although generic entry is not likely until 1998, the impact of a generic 20 mEq product would be significant, especially for the sales subject to mandatory generic substitution laws, Medicaid and managed care."

Do you see that?

A. Yes.

Q. And here, this is a document -- you testified this is a marketing backgrounder?

A. Yes.

Q. Here, the statement is specific to the impact of generics that are of the 20 mEq variety, correct?

A. Yes.

Q. Okay. This isn't talking about all the other generics that are on the market for potassium chloride.

A. No.

Q. This is specific to just generic 20 mEq.

A. I believe so.

Q. And it says that it would be significant

especially for sales subject to mandatory generic substitution laws, Medicaid and managed care, correct?

A. Yes.

Q. Now, the generic substitution laws, the only generic that can be substituted for 20 mEq is a generic 20 mEq, correct?

A. An equivalently A-rated -- and I don't -- I'm not a generic substitution law expert.

Q. Okay.

A. But my understanding is that they would have to be, quote unquote, "A-rated."

Q. Okay. So, the only generics that can be substituted for a 20 mEq -- for the K-Dur product that is a 20 mEq is another generic that is a 20 mEq.

A. Unless the pharmacist contacted the physician and basically said, can I substitute two 10s for a 20, which often happened.

Q. Okay. And at this time, there were no other 20 mEq generics available.

A. Not that I was aware of.

Q. If you could turn to CX 18, please, and again, this is the 1997 K-Dur marketing plan?

A. Yes.

Q. And I believe Ms. Shores was asking you some questions about all the different potassium products

that are out there, correct? Do you recall that?

A. Yes.

Q. Okay. And I think you referred to it as an undifferentiated market.

A. Yes.

Q. And you said it was hard to differentiate your K-Dur product from the others. Is that right?

A. We tried.

Q. Okay. If you could turn back to page SP 2300040, the fourth page of the document, it says "Vision" at the top.

Do you see that?

A. I do.

Q. Okay. The first sentence says, "K-Dur remains the only once-daily 20 mEq potassium replacement tablet on the market."

Do you see that?

A. I do.

Q. So, it's the only once-daily 20 mEq.

A. That was our position. I mean, that was our vision of it, yes. It's the only 20 mEq.

Q. Okay. So, that's a true statement, it's the only 20 mEq.

A. At that time, yes.

Q. The only once-daily 20 mEq.

A. At that time, yes, um-hum.

Q. And that differentiates it from all these other drugs on the market.

A. That was our position to brand that, yes, that was what we were trying to do.

Q. That's how you marketed the drug.

A. Yes.

Q. Okay. The next sentence says, "These features combined with the versatility in dosing for K-Dur 20's microencapsulation technology have helped our sales and marketing team keep K-Dur 20 at the top of the potassium market."

So, "these features" is referring back to the once daily, correct?

A. No, we actually positioned this because we said you could break it in half, you could swill it in water, you could take it partially. So, we got, quote unquote -- or you could sip it with a straw, we even had cool little straws that allowed you to sip it with. So, the flexibility in dosing, whether you had 20 mEq, 30 mEq, 40 mEq, was we thought -- we tried to establish it as a distinguishing feature, yes.

Q. Okay. You used those features to distinguish or differentiate your product from other products?

A. That was our intention.

Q. Now, you had also talked about there were price constraints on your product. Is that correct?

A. Yes.

Q. Okay. Now, despite those price constraints, did you generally raise the price of K-Dur 20 every year?

A. I don't recall exactly how much, but we generally tried to raise the price, yes.

Q. Okay. Do you recall if you raised the price between 1995 and 1996?

A. I don't. We likely did.

Q. Okay. How about '96 to '97?

A. I don't recall exactly, but we likely did.

Q. '97 to '98?

A. I don't recall.

Q. Is it likely?

A. Likely.

Q. How about '99 to -- did I stop at '98? Okay, how about '98 to '99?

A. Actually, I can't even comment on '97 and '98. I don't think I had the product then.

Q. Okay, that's fair.

A. But for the couple -- two-three years, I think we took an -- I think we took a price increase. And actually, my recollection, it was smaller than some of

the other MI products.

Q. Okay, but for the years you can recall, you increased the price of K-Dur 20, correct?

A. Yes. And K-Dur 10, too.

Q. Okay, thank you.

Let's turn to Niaspan. Now, towards the end of your testimony, we heard you talk about some sales forecasts that you had done while you were evaluating Niaspan, correct?

A. Yes.

Q. And you had testified that there was one certain set of sales projections that you felt were the most accurate.

A. Yes.

Q. Let me show you a demonstrative that Schering used in their opening statement in the litigation with certain sales figures, and just tell me -- are these the same sales figures Ms. Shores took you through that you said were the most accurate?

A. I believe that they are.

Q. Okay. If you like, we can turn back to I believe it is CX 550 and you could check. I believe that this is your base case price scenario II.

A. Let me just make sure I've got the right one. Yes, they are the same.

Q. Okay. And Paula, if we could pull up CX 550, please.

Okay, and if you could just focus in on the left-hand column, which shows the assumptions that you looked at --

A. Yes.

Q. I'm sorry, Paula, up under where it says, "Ray's Niaspan Sales Forecast," the listing of about eight or nine items down the left there. Yeah, those. That's great.

Okay, and I think you already went through this with Ms. Shores and you told us about how you did this analysis.

A. Yes.

Q. And it's a fairly detailed analysis, isn't it?

A. Yes, not inconsistent with similar analysis, but yes.

Q. Is this generally how you do your sales forecasts?

A. Generally.

Q. And this is how you do your sales forecasts when you consider in-licensing a drug?

A. Yes.

Q. Okay. And in doing this sales forecast, you looked at two different scenarios. Is that right?

A. Yes.

Q. And is that also something standard, to look at multiple price scenarios?

A. I wouldn't characterize it as standard. It depends on the nature of the product. If you have a reference price, you have one, and you can use it. If you don't, often times you can't establish an existing product in the market, and so therefore you have to do one of a number of things. You either have to do some marketing research to assess it, you have to take a good, you know, educated business guess, or you have to find -- well, frankly, those are the two big things. You have to, you know, use your best judgment to come up with a price. In this case, we had some reference prices that we used.

Q. Okay. In doing similar analyses before for Schering, have you looked at multiple pricing scenarios?

A. Yes, but I don't recall looking at them -- you know, I looked at the generic gemfibrozil and the Niaspan. I would normally just have one price, generally, in the ones I had done.

Q. Okay. Paula, if you could pull up CX 1040.

MS. KATZ: Are you sure that's the number?

MR. SILBER: That doesn't look right to me. I

think I've got it in a binder. I apologize, Your Honor.

JUDGE CHAPPELL: Is that an exhibit?

MR. SILBER: Excuse me?

JUDGE CHAPPELL: Has that one been admitted into evidence?

MR. SILBER: It's quite persuasive, isn't it? I'm sorry, it's 1044, if you could just focus in on the top part where the language is.

Your Honor, I apologize, I do not have an additional copy. I can give my copy to respondents' counsel.

JUDGE CHAPPELL: If they want it, yes. I can see it on the monitor.

MR. SILBER: Okay. If you would like to take a look at it --

MS. SHORES: I'll just get it from our set.

MR. SILBER: Okay, thank you.

BY MR. SILBER:

Q. Mr. Russo, have you seen this document before?

A. I don't recall it.

Q. Okay.

MS. SHORES: Your Honor -- I'm sorry, Seth, but I would ask that the witness be provided a whole document if you are going to ask him questions about

it.

MR. SILBER: Surely.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. SILBER:

Q. Mr. Russo, have you had a chance to look at this?

A. Briefly.

Q. Okay. And do you recognize the document?

A. I don't.

Q. Okay, let's look at the cover of it. It says it's from Tom Lauda to Ray Kapur.

A. Yes.

Q. You're familiar with those individuals?

A. I am.

Q. And the date is June 17, 1997. Do you see that?

A. Yes.

Q. And the language on the cover sheet says, "Please find attached the commercial assessment for Niacin. If you have any questions, please contact myself or Jim Audibert."

Do you see that?

A. Yes.

Q. Are you familiar with an evaluation Mr.

Audibert did for a drug called Niacor-SR?

A. I knew he was looking at that product, yes.

Q. Okay. Do you know whether he did sales projections for that drug?

A. I believe he did.

Q. Okay. I'd like to show you the sales projections in this document, if you could look back to page SP 1600046.

Paula, if we could pull that up.

Do you see it says "Table I"?

A. Yes.

Q. And here -- and take your time looking at this -- it represents that this is worldwide sales for the cholesterol-lowering market. Do you see that?

A. It says ex-U.S., Mexico and Canada.

Q. Yes, I'm sorry, thank you.

And it's got sales listed for 1996 as $4 billion?

A. Right.

Q. Okay. And then underneath it's got percent change, do you see that?

A. Yes.

Q. And the number of sales for this worldwide market, ex-U.S., Mexico and Canada, increases slightly for each year by that percent change. Is that what you

believe this document is doing?

A. It shows a change for four years of 15 percent and then a deceleration to 10 percent out to 2007.

Q. Okay. So, this page shows the worldwide market, the sales for the cholesterol-lowering market, correct?

A. Ex-U.S.

Q. Ex-U.S., absolutely.

Okay, now, the next page, you can look at it, which is SP 1600047, it's labeled Table II, and it's labeled Niacor-SR Sales. Do you see that?

A. Yes.

Q. And the sales for 1999 are $45 million. Do you see that?

A. Yes.

Q. Okay. And from looking at the last page, can you tell where that figure was derived from? It says the market share on Table II is 0.75 percent, and in 1999, there was $6 billion in sales.

A. Well, if I'm doing my math right, it looks like he took 0.75 times the $4 billion. Is that right? Is that what he's doing?

Q. Actually, I think that is correct, okay.

So, here, in this analysis, does it appear as though someone is taking a worldwide ex-U.S. market and

coming up with sales projections just by multiplying that market by some market share?

A. I didn't do this, so I don't know.

Q. I'm just asking if that's what it looks like to you.

A. I'll accept your characterization of that. I don't know.

Q. Okay. How does this analysis for Niacor-SR compare with the way you did your sales forecast?

A. As I told you, I didn't do this sales forecast, so I don't know.

Q. Can you looking at this -- were all the steps that you did, were they present in this analysis for Niacor-SR?

A. I can't tell, because I didn't do this analysis.

Q. Okay. In this analysis, did the individual who did it, did they determine the total patients eligible for the drug?

A. I can't tell. They may have done that, and they may have summarized it for senior management. I can't tell.

Q. Okay.

A. I can't read their minds.

Q. You can't tell from this document?

A. I can't tell from this document.
Q. Okay. And you can't tell whether this individual determined the number of patients receiving therapy, as you had done for your analysis for Niaspan.
A. I can't tell.
Q. Okay. And you can't tell whether this individual determined the number of patients receiving niacin as you did in your analysis.
A. Again, having seen this now for the first time and not having discussed this with whomever did this, I couldn't tell what he did or she did.
Q. Okay. And you can't tell whether this individual determined the number of patients receiving the actual drug here, Niacor-SR, as you did in your analysis for Niaspan.
A. I can't tell.
Q. Okay. And in doing your analysis for Niaspan, there were six different sales projections, correct, between what you had done and what Ms. DeMola had done. Is that right?
A. I mean, there -- in my mind, there are three. We basically looked at three scenarios, which we'll do base case, some upside and -- I actually did two of the three, so I did two of the three and the downside was done by Toni.

Q. Okay, but those three sales forecasts were done for two separate pricing scenarios.

A. Yes.

Q. So, you came up with six different sales forecasts?

A. Yes. I came up with four.

Q. Okay. And in this exhibit, CX 1044, how many sales forecasts are there?

A. Let's see, I see one on Table I and one on Table II.

Q. Well, sales forecasts for the drug, not for the market. It's only Table II that provides a single sales force -- sales forecast. Is that correct?

A. Yes.

Q. Okay. Like Ms. Shores, we have also prepared a slide to try to make your sales projection spreadsheet a little easier to read.

A. Okay.

Q. Paula, if you could bring that up.

I don't know, again, if this helps or not. We all have the same problem with this document, but this is CX 550. You can look at it in your binder or you can look at it up there on the screen.

Now, it was your testimony that -- what we've got here is titled Ray's Forecast - Base, Price

Scenario II, and this was in your testimony the most reasonable?

A. Yes.

Q. Okay. And this was the same numbers that were in this demonstrative that I had shown you earlier. Is that right?

A. Yes.

Q. Okay. Was there agreement among your colleagues that this was the most realistic estimate of sales projections?

A. Among my colleagues? I was the senior director of marketing, so I got to have the final say. So, I -- I agree with it, Marty agreed with it, it was included -- it was the one that was carried forward to the important financial analysis. And remember, what these are, this is -- these are spreadsheets. This is Lotus spreadsheets. So, this is backup documents. It's hard for me to tell from a backup document which is basically the worksheet as to what went into a document that I'm not familiar with, so I'm not clear on that one.

Q. Okay. Now, you asked Ms. DeMola to do a set of forecasts here, didn't you?

A. Well, Toni did it independently. I mean, she often times will include her market research

assessment.

Q. Okay. And sometimes do you rely on this?

A. Sometimes we use them to, you know, determine upside and downside potential, yes.

Q. Okay. And her forecasts were lower than yours; they were the downside projections, correct?

A. That's correct.

Q. Okay. So, that's a separate set of projections that were less than yours, correct?

A. Yes.

Q. Now, you also said you were her boss, so it seems as though your numbers prevailed?

A. Well, I wasn't actually her boss.

Q. Okay.

A. But I was the expert in the cardiovascular area. Toni was responsible for all therapy areas. So, she was the head of marketing research; I was the head of cardiovascular marketing.

Q. And did Mr. Driscoll -- who is Mr. Driscoll again?

A. He was the vice president of sales and marketing for Key Pharmaceuticals at that time.

Q. Is he your boss?

A. He is.

Q. Did he agree with your sales projections?

A. I believe he did.

Q. Let me show you some testimony from your deposition.

JUDGE CHAPPELL: Mr. Silber, how much more do you have?

MR. SILBER: I would estimate 30 to 40 minutes, so --

JUDGE CHAPPELL: Okay. Is this a good time for a break?

MR. SILBER: I will wrap up this section dealing with sales forecasts probably within five minutes, and then the rest is kind of a distinct segment, so if I could proceed and finish this.

JUDGE CHAPPELL: Okay, let me know when it's a -- when you finish this line of questioning, then.

MR. SILBER: I will, Your Honor, thank you.

BY MR. SILBER:

Q. Okay, let me show you this testimony from your deposition at page 163, and if you want a copy of it, I can provide that to you.

A. Okay.

Q. It says:

"ANSWER: Well, we discussed the whole situation. I think Marty and I basically agreed but I was, frankly, a little more bullish on the upside

potential and I wanted a product that was a cardiovascular complement to future strategic initiatives so I probably was a little bit more positive than Marty."

So, there really wasn't complete agreement between the two of you.

A. No, I think I said we had basic agreement. Marty and I basically agreed.

Q. Okay. Do you know whether Mr. Driscoll had ever stated on his own what he thought the sales projections were for Niaspan?

A. I do not.

Q. Okay. Would you be surprised if he said that he thought the maximum sales potential for this drug was $60 to $70 million?

A. A little bit.

Q. Okay. Let me show you some testimony from Mr. Driscoll's investigational hearing, which is just another word for deposition.

A. Okay, okay.

Q. And here, the question to Mr. Driscoll is:

"QUESTION: When you were having the discussions with Kos, did you ever come up with a dollar figure you were projecting for the potential sales of this product?

"ANSWER: For their product?

"QUESTION: Yes.

"ANSWER: Oh, yes.

"QUESTION: And what were your projections?

"ANSWER: Mine, my projections were that this product based on the profile I had seen -- and again based on the information available to me, we had not gone go a heavy due diligence, had not been given the benefit of broad information, but based on what was available to me, my sense of that product and profile was max 60 to $70 million product one day."

So, in this testimony, is Mr. Driscoll saying that the maximum sales potential for this drug is $60 to $70 million?

MS. SHORES: Your Honor, I object to that. I think the testimony speaks for itself. If he wants to ask him whether he agrees with it, that's one thing. The transcript is on the screen.

JUDGE CHAPPELL: It's a fair question. I'll overrule the objection. If the witness doesn't agree, he can say no. If he is -- if you're right, Ms. Shores, and he's misstating something, the witness can take care of it.

THE WITNESS: Could you repeat --

MR. SILBER: Would you like the question read

back, please?

Susanne, if you can read it, please.

(The record was read as follows:)

"QUESTION: So, in this testimony, is Mr. Driscoll saying that the maximum sales potential for this drug is $60 to $70 million?"

THE WITNESS: It's not clear. I mean, here he says based on what was available to me, my sense of the product and the profile was max 60 to 70 million product one day, and I don't understand what that exactly means. I mean, is that one day sales, per annum, total? I don't know.

BY MR. SILBER:

Q. Do you think Niaspan could have had one-day sales of $60 to $70 million a day?

A. No, I don't.

Q. Okay. Do you think it's likely he's talking about annual sales?

A. It's likely, but I don't know if he's talking max early launch, max life of the product. It's hard for me to assume what Marty was thinking.

Q. But he was saying something about the maximum of $60 to $70 million annually for Niaspan.

A. If that's what he said, I think that's low.

Q. That's your opinion?

A. That's my opinion, yes.
Q. And Mr. Driscoll is your boss?
A. Mr. Driscoll is my boss, but I'm the head of cardiovascular marketing.
Q. Who made the ultimate decision to discontinue discussions with Kos about Niaspan?
A. I believe Rich Zahn did. He agreed that we should no longer continue the discussion.
Q. Was that based upon a memo that Mr. Driscoll had written to Mr. Zahn?
A. I believe so, and probably discussions with Rich.
Q. Okay. So, Mr. Driscoll recommended to Mr. Zahn to drop Niaspan?
A. Yes.
Q. To drop discussions with Kos about Niaspan?
A. Yes, I believe so.
Q. So, that was his recommendation to his boss.
A. Yes.
Q. Now, just assume with me for a moment --
A. May I make a clarification please?
Q. Sure.
A. And I'm not sure what Marty means here. Is that the sales we would achieve as a company in a co-promotion? Is that the total sales potential of the

product? So, it's not clear to me that we necessarily disagree. If this is one-half of the sales potential split between a co-promotion, our numbers are fairly close. So, I don't know exactly what Marty meant in this case.

Q. Okay. But if you take the $60 to $70 million to be the full sales for Niaspan, this is lower than your projection. Is that right?

A. If you take them to be the full sales. Remember, we're looking at a co-promotion arrangement.

Q. Right.

A. Okay.

MR. SILBER: Your Honor, that's all I have for this part, so if you would like to take a break, this would be a good time.

JUDGE CHAPPELL: Okay, let's take our afternoon break. We will be in recess until 4:20.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Silber, you may proceed.

MR. SILBER: Thank you, Your Honor.

BY MR. SILBER:

Q. If we could go back to K-Dur for just a moment, CX 17 in your binder, the marketing backgrounder.

Now, you had told us about substantial promotional efforts that Schering had undertaken for

K-Dur. Do you recall that testimony?

A. Yes.

Q. And I believe you had said there was about $20 million in promotional spending?

A. Approximately.

Q. If you could look at SP 003546, it's regular page number 6 at the bottom, and about two-thirds of the way down the page --

MS. SHORES: Excuse me, Seth, you said 3546?

MR. SILBER: Yes.

MS. SHORES: And you're in CX 17?

MR. SILBER: Sixteen.

MS. SHORES: I didn't use CX 16, so I don't think the witness has it in front of him.

MR. SILBER: Okay, let me hand it to the witness, then. Do you want to take a look at it first?

(Counsel conferring.)

BY MR. SILBER:

Q. Okay, I think it's the same document. I think CX 16 and CX 17 are the same document.

A. I see it.

Q. And if you can look under Forecast. Paula, if you could pull up that paragraph under Forecast.

Okay, in the last line it says, "The forecast also assumes that there are no new product

introductions and K-DUR continues to receive minimal detail and promotional support."

So, here, rather than saying you're having a substantial promotional support, you're talking about minimal detail and promotional support. Is that correct?

A. Remember what this is. This is in preparation of the marketing plan. So, what we do as good marketers, we make our case to get additional spending and additional field force support. So, this is actually done before the approval of the marketing budgets. So, what JoAnn was doing in this case was basically giving a baseline forecast with no marketing support. That was my understanding.

Q. But this was a document done for planning purposes?

A. Yeah, before the marketing plan is put together.

Q. And in this document it talks about minimal detail and promotional support. Is that correct?

A. Yes.

Q. Let me show you another document, which is CX 695, which I do not have another copy, a colleague just gave it to me. Let me give it to Ms. Shores to look at first.

Your Honor, if I may approach?

JUDGE CHAPPELL: Yes, you may.

BY MR. SILBER:

Q. I just want to give you an opportunity to look at the whole document to make sure that you know what it is.

A. Sure.

Q. And I guess if you can tell me if you recognize this document.

A. These are internal product margin reports.

Q. Okay. And you've seen this document -- document or documents of this type before?

A. I have.

Q. Okay. And I wanted to focus your attention on the third page of the document, which is SP 020698, okay? And what I wanted you to look at was the year to date figures, which is four columns over as far as the numbers, it's the fifth column of the document.

A. Right.

Q. Next to Total Selling -- I'm sorry, next to Total Promotion, which is about two-thirds down the page, there's a figure of $5,134,000?

A. Yes.

Q. Do you see that?

A. I do.

Q. And that is the total promotion for the year 1997 for K-Dur?

A. I believe so. I believe -- I'm not sure, but it looks like it. Generally they're captured this way, yes.

Q. Okay. And three lines down is the Total Selling figure, which is $1,206,000. Is that correct?

A. That says it's field selling, yes.

Q. And that totals up to a little more than $6 million?

A. Approximately, yes.

Q. Which is substantially less than the $20 million figure that you had discussed with Ms. Shores?

A. I had all-in $20 million. If you will see, there's cash discount, freight, and I'm not sure that this captures all third parties. I don't -- this is an allocation that the finance folks do. I don't recall when we brought on a third party to promote K-Dur, but it looks less than my estimated figure, yes.

Q. Okay, you can set that aside. If you still want to look at it, go ahead.

A. Yeah, because you picked one year, and there are other years where the total promotion in '98, for example, was almost $7 million. So, there was a range of between $3 and it looks like $8 million on

promotion, and field selling, this might have only captured the field selling that was allocated from the field force. It might not have captured third-party costs. So, I'm not sure.

Q. But the year you discussed with Ms. Shores was 1997. Is that right?

A. That was a forecast for '97. That was our recommendation to spend, yes.

Q. Okay, okay, thank you. All right, now we can turn back to Niaspan.

A. Okay.

Q. If you could look in the binder you have to CX 546, and Paula, if you could pull that up, please.

MS. SHORES: Excuse me, Seth, I don't know what binder you have.

MR. SILBER: I'm using your binder. It's not in your binder?

MS. SHORES: No.

MR. SILBER: Your Honor, may I approach?

JUDGE CHAPPELL: Yes, you may.

MR. SILBER: Your Honor, would you like a binder? We are going to be putting them up on the screen.

JUDGE CHAPPELL: I don't need one if it's on the screen, thank you.

BY MR. SILBER:

Q. Okay, do you have CX 546 in front of you, Mr. Russo?

A. Yes.

Q. Okay. And did you prepare this memorandum?

A. Yes.

Q. Okay. It says next to the "From" line your name?

A. Yes.

Q. And the subject is "Niaspan Opportunity"?

A. Yes.

Q. And the date is March 26th, 1997?

A. Yes.

Q. And you drafted this memorandum during your participation in the evaluation of Niaspan for Schering?

A. Yes.

Q. If you go about halfway down the page below where it says 1, 2, 3, there's a line that says, "For this opportunity to be viable for SGP, a number of issues must be resolved."

Do you see that?

A. I do.

Q. And SGP refers to Schering-Plough?

A. Yes.

Q. And it says that certain issues must be resolved for the opportunity to be viable.

A. Yes.

Q. Okay. And it then lists three separate items, and if you look under the third item, it says, "Due diligence validation of issues regarding," and those are issues according to the language above that must be resolved for the opportunity to be viable. Is that correct?

A. Yes.

Q. And it says "Patent status" next to that. Do you see that?

A. Yes.

Q. Why would this need to be resolved for Niaspan?

A. I mean, just as a -- you know, we would look at that just to see if, in fact, their formulation patent was reasonable. They had a -- niacin was not a patentable drug, and so we probably would have looked at their formulation patent. So, that makes sense.

Q. Okay. Was that ever resolved for Niaspan?

A. I don't believe we did. I don't believe we went that far.

Q. Okay. The next is finalized labeling. Why would that issue need to be resolved for Niaspan?

A. Well, recall that they had submitted

recommended labeling. So, before we would move forward, we would want to see what the FDA had given them back.

Q. Why would you want to see what the FDA had given them back?

A. Just to see that what they had proposed is what they had received.

Q. And was that ever resolved for Niaspan?

A. We discontinued the talks before they got approval.

Q. What about the manufacturing capabilities, why would that need to be resolved for Niaspan?

A. Well, for Niaspan, for this company, they had never made a product before. So, they didn't have the history of manufacturing. I'm not recalling where they were going to make it. Sometimes we'll make these products, but particularly a small company -- and these -- you know, they vary based on the nature of the company.

In this particular case, we wanted to make sure that they could make it if, in fact, we were going to move forward on that.

Q. And was that ever resolved for Niaspan?

A. I believe we knew their third party, so we found out who their manufacturer was and were

comfortable with it.

Q. Okay. What about product liability, why would that need to be resolved?

A. Well, again, this is a small company. They -- this is going to be their first product to market. So, in case of a recall, we just wanted to make sure that, in fact, they had enough coverage.

Q. And was that issue ever resolved for Niaspan?

A. We didn't get that far.

Q. Okay. So, of these four issues, you think manufacturing capabilities may have been resolved?

A. I believe so.

Q. But the other three were never resolved.

A. We didn't -- we didn't move those forward, no.

Q. Okay.

A. On the patent status, I'm not sure if there was a patent review, but again, not soon after this we discontinued discussions, so there was no need to go further on any of those or on the remainder of those.

Q. Okay. If you would look at the last paragraph on the page, and Paula, if you could just pull that up.

It says, "These issues need to be reviewed and more completely understood before a deal could be made." And when it says "these issues," it's referring to all these issues listed above, including patent

status, finalized labeling, manufacturing capabilities and product liability, correct?

A. Yes.

Q. And you didn't resolve patent status, finalized labeling, product liability, correct?

MS. SHORES: Objection, asked and answered, Your Honor. He's asked the same question a number of times.

MR. SILBER: It's probably accurate, Your Honor. I'll move on.

JUDGE CHAPPELL: Thank you.

MR. SILBER: I'll withdraw the question.

BY MR. SILBER:

Q. Per this statement, unless these issues were reviewed, a deal could not be made, meaning that the Niaspan deal could not be made.

A. I mean, I think I stated, unless they were reviewed and better understood, we couldn't move forward. So, we were in the process of trying to understand them and in the process of offering broad deal terms.

Q. Okay. And a little further down in that paragraph it says, "We would of course subject any deal to this criteria."

Do you see that?

A. Yes.

Q. So -- and the criteria is everything we've discussed above, the due diligence and validation issues. Is that right?

A. That's probably not an accurate description. I've done many deals that didn't subject the review to those criteria, but that -- in this memo, it probably considers those, yes.

Q. Okay. So, in this memo you state, "We would of course subject any deal to this criteria."

A. Right.

Q. Okay. If we could go to CX 576 -- I'm sorry, if you want to look at that document further, please go ahead.

A. Okay.

Q. CX 576 is the next document, and I -- this is the document from Decker Research Associates that I believe Ms. Shores showed you or at least the cover page on your direct. Do you recall that?

A. Yes.

Q. And the title for this is, "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders, Telephone Interviews with Lipid Specialists," and it's dated April 1997.

Do you see that?

A. Yes.

Q. Does that mean you received this report in April 1997?

A. Yes, I believe so.

Q. Okay. This was part of the review you had done on Niaspan?

A. Yes.

Q. And you had indicated you had spent a significant sum of money on this document.

A. That was my belief, yes.

Q. Okay. So, you would consider this document to be reliable?

A. I would.

Q. Okay. And this document was based upon I believe you indicated interviews with ten lipidologists?

A. We did two things. We had an advisory board committee and then we did some telephone interviews.

Q. Okay. And that -- the ten interviews were with lipidologists?

A. I'm going to take a closer look at this.

Q. Yeah, if you like, the second page of the document, which is SP 020708, the paragraph there, about two-thirds of the way down, says, "This report presents findings from a series of ten one-on-one depth

interviews with lipid experts from Key's SCH 28235 Advisory Board."

A. Okay.

Q. So, that indicates that this was based upon interviews with ten lipidologists from Schering's advisory board?

A. Yes.

Q. And this was done in April 1997.

A. I don't recall if the advisory board was, but the report was.

Q. Okay. And that was two months before Schering licensed Niacor-SR?

A. I don't know.

Q. You don't know when Schering licensed Niacor-SR?

A. I do not know.

Q. If you could turn to SP 020709, and Paula, if you could pull up the second paragraph on that page.

A. I'm sorry, what's the reference?

Q. It's page number 2 of the document.

A. Okay.

Q. It says at the top, "Conclusions and Recommendations."

A. I have it.

Q. The second paragraph, the first line says,

"Experts reported that the flushing patients experience with immediate release niacin can be handled and that they avoid use of sustained release preparations, which cause less flushing, because of diminished efficacy and concern regarding liver toxicity."

So, this statement indicates that these experts avoid use of sustained release preparations. Is that right?

A. The currently available ones, that's correct. There were problems with them.

Q. Okay. And Niaspan was a sustained release preparation?

A. But with a different delivery system. That's what we were going for. Yes.

Q. Okay. And it says here that experts avoid sustained release because of diminished efficacy.

A. Right, they would have to -- I don't believe the current sustained release product had good clinical trials, so again, they weren't getting good blood levels, they didn't have good phase III efforts. So, I -- they had a bad experience with the currently available sustained release technology.

Remember, there are a lot of delivery systems, and the amount of product that gets into your bloodstream is basically dependent on the type of

delivery system. If it's a weak delivery system that tends to dump the product in early, and I'm not -- I'm not very familiar with that sustained release technology or the one that they had used, it could have serious problems, and they would likely avoid it.

Q. Okay. So, the experts were talking about those problems in this statement?

A. Yes.

Q. Okay. And it says that these experts avoid sustained release because of concerns regarding liver toxicity. Is that right?

A. Yes.

Q. Okay. If you could turn forward two pages to SP 20711, it's page 4 of the document, and Paula, if you could pull up paragraph 9.

In the first line it says, "Physicians also voiced numerous concerns and questions."

Do you see that?

A. Yes.

Q. And then it goes on to say, "They need 'compelling evidence' to support the safety and side effect claims which 'go against our experience.'"

What safety and side effect claims are being referred to here?

A. I mean, it's my sense that their current

experience with that weak sustained release product that was available at the time was primarily the flushing and liver toxicity.

Q. Okay. You keep talking about the current product.

A. Right.

Q. What are you speaking to?

A. There was a product that was on the market that they had experience with that was, quote unquote, a "sustained release niacin."

Q. Okay, and these doctors are reporting upon their experience with what was available in sustained release?

A. Yes.

Q. And they're voicing their concerns and questions about those products?

A. That's my understanding, yes.

Q. Okay. And then, based upon those concerns, they say they need compelling evidence to support the safety and side effect claims which go against our experience.

A. Correct.

Q. Who at Schering would have been involved in determining whether such compelling evidence existed for Niaspan?

A. Myself, I mean likely Jim, someone in the Schering-Plough Research Institute, likely Rick Veltri. I mean, basically what they're looking for is clinical data, clinical research data, standard, good, well-controlled clinical trials, and that's -- in this therapy area, in cardiovascular medicine, that's compelling evidence.

Q. Okay. So, SPRI would have been involved in evaluating it?

A. Likely. I mean, if there was no printed third-party materials, we would have asked them for an opinion, likely.

Q. Now, with regard to niacin, did you ever find that there was compelling evidence to support the safety and side effects claims?

A. Well, the Niaspan people believed that they had overcome the side effect issues and that there was -- their one published paper that I believe demonstrated a certain level of efficacy and I believe demonstrated that they had ameliorated some of the side effects that had been seen in the early sustained releases. So, I believe they felt that they had.

Q. Okay, but the question was, did Schering feel that there was compelling evidence to support the safety and side effect claim for Niaspan?

A. I think we needed to see more of their clinical data. We were -- you know, was it compelling, you know, I can't say. Was there evidence that they were working on that, yes, their clinical study demonstrated that they had reduced the incidence of side effects. So, that was reasonable. They had a good titration pack, which is another standard way that cardiovascular medicines tend to avoid, you know, overdosing. So, there was reasonable evidence that they had worked in the direction to minimize those side effects.

Q. When you concluded your evaluation of Niaspan or when the Schering team concluded their evaluation, did they conclude that there was sufficient evidence to substantiate Kos' claims regarding flushing and liver toxicity?

A. I think we were getting comfortable with that. We -- that was not a show-stopper for us. If, in fact, we could have gotten to better deal terms and a closer arrangement on that, we would have worked with them, and I think we could have resolved some of the side effect issues, but that's my opinion. That's my sense of it.

Q. Okay. Do you know what Mr. Driscoll's opinion was on that?

A. I do not.

Q. Okay. Okay, let's turn back to -- forward in the document to SP 020715, which is page 8 of the document. Okay, the large paragraph in the middle, Paula, if you could pull that up.

Okay, here the paragraph starts that, "Niacin is relatively inexpensive and 'does all the right things.' It lowers LDLs and triglycerides and raises HDLs. It is effective as a first line therapy in patients with only moderately elevated LDLs. Experts stress that niacin is the best agent we have for raising HDLs, rarely a primary problem; one physician indicated that niacin is unique in its effect on apoprotein A.

So, these are some of the potential benefits of the drug, right?

A. Yes.

Q. Now, the next sentence says, "There are numerous negatives offsetting these recognized benefits."

Do you see that?

A. Yes.

Q. And it lists among these negatives a very high incidence of flushing at initiation of therapy, complex titration requirements which place demands on physician and patient, contraindications in diabetics and

patients with gout, varying bioavailability from manufacturer to manufacturer, liver toxicity, especially with the sustained release preparations.

Are these all negatives that you are aware of?

A. By and large, yes, um-hum.

Q. And these are the negatives that your panel of lipidologists is pointing out to Schering in the study you commissioned?

A. They are pointing it out for niacins in general, yes.

Q. Were these problems with Niaspan?

A. With -- this is what we needed to hear. This is what we wanted to hope to overcome, because if you look there, this is the very issue. Varying bioavailability from manufacturer to manufacturer; complex titration requirements, they were trying to overcome that; liver toxicity, they were overcoming that, especially with the sustained release preparations. So, we were trying to see what the current perception was and if, in fact, Niaspan could overcome them, and the positioning that Kos had was that if they could, that was a valuable product.

Q. The last sentence of this paragraph says, "Physicians pointed out that niacin and, particularly, sustained release niacin, has such a bad reputation

among primary care physicians that successful marketing of Niaspan will require compelling data and strong support from lipid specialists."

So, here they're talking about to successfully market Niaspan, you need to overcome all these things. Is that right?

A. Yes.

Q. And did you present the clinical data that you had on Niaspan to these lipidologists?

A. I don't recall if we presented the Niaspan clinical study. I think we presented the one paper that we had available is my recollection, but I'm not sure.

Q. And that one paper was the same data that you were reviewing internally?

A. Right.

Q. Okay, let's turn to page 10 of this document, which is SP 020717. Okay, and the bottom paragraph, Paula, if you could pull that up.

It says, "Because of niacin's history and, especially, the safety issue with sustained release niacin, Niaspan trial data will be scrutinized very carefully. Based on the one study we could show them --" does that clarify whether you provided them clinical data?

A. Yeah, it was likely we showed the published clinical data.

Q. And this was the same data that you were reviewing internally?

A. I believe so.

Q. And it goes on to say, "the lipid experts identified Niaspan as a promising agent, possibly a truly superior niacin, but they remained unconvinced on the issues of liver toxicity, especially in combination with a statin, and side effects (flushing and nausea)."

So, based upon their review of this data, the same data you had, they remained unconvinced on the issue of liver toxicity and side effects.

A. That's correct. What's interesting is there is now a niacin-statin combination. So, we got the compelling data, so -- we were aware that the current dumping -- there was a sustained release product out there that would just dose-dump, and it was very problematic, and they had a bad flavor in their mouth. So, these were the guys we would have had to convince, and frankly, it was part of the reason we wanted to see the rest of the NDA filing for Niaspan, because if there was additional data that would support this positioning, or importantly, if we saw the final labeling and it wasn't contraindicated in some of these

issues or the side effect profile was better characterized, we thought we had a very good product.

Q. Now, what you're talking about, a combination of niacin and statin, that's data available in the year 2000.

A. Yeah, that's a recent product.

Q. Certainly data not available in June of 1997.

A. Well, actually, there were studies that went back combining the two products that showed that there was at lower levels some opportunity for this combination, but it was not in a fixed-dose combination. There were separate additive compounds.

Q. Okay, but these lipidologists that you had retained here would have been familiar with that.

A. They would have -- they often used combined therapy, so they would have known that, yes.

Q. So, even knowing that, they said that they remained unconvinced on the issue of liver toxicity, especially in combination with a statin, and side effects, such as flushing and nausea.

A. Right, I think we were waiting to see the package insert.

Q. Okay, and this was their statement in April of 1997 based upon the information you had provided and what they knew about sustained release niacin drugs.

A. Yeah, their experience, not this product, but their experience, yes.

Q. And this was just two months before Schering paid $60 million for Niacor-SR.

A. I don't -- I don't know that.

Q. Okay, if you could turn to CX 1047, and this is another document that Ms. Shores showed you during your direct. Do you recall that?

A. Let's see, is this the contact that -- the visit? Yes.

Q. Okay. And this document is a contact report about your visit to Kos in Miami in April 1997.

A. Yes.

Q. And you participated in this meeting along with Toni DeMola, Karin Gast and Dave Grewcock. Is that correct?

A. Yes.

Q. Let me turn to the third page of this document, which is SP 002748, and Paula, if you could pull up the paragraph under Global Options.

Okay, do you recall discussions about a global option?

A. Yeah, we had some general discussions as to if this was a worldwide opportunity.

Q. Okay. And here, it says, "We suggested that,

since time is of the essence in the U.S., we concentrate on this territory first and leave ex-U.S. discussions for later."

Is that right?

A. Yes.

Q. So, that was Schering's discussion, to focus on the U.S. and not discuss licensing ex-U.S.?

A. Right, because there were -- they had a pending approval, and if the negotiations were to go on further, we didn't want to tie the two up. They had a pending approval within months was my -- was my recollection at the time.

Q. Okay. This goes on to say, "Bell did not have a problem with this," and if you could just remind us who Bell is.

A. That's Dan Bell. I believe he's the COO of Kos at the time.

Q. And then it says, "He realizes that the market potential in Europe (and probably also in Japan) is quite limited."

Do you recall him saying that?

A. I do not.

Q. But it's stated in a summary of this memo that was prepared by a Schering employee?

A. That's what's stated here.

Q. Okay. And he's speaking to Europe and Japan as having limited market potential.

A. I'm not sure. I mean, it could have been the ability to get it approved, the time line, the investment. So, I'm not sure what he's referring to there.

Q. Do you know what territories the license for Niacor-SR covered?

A. I do not.

Q. Well, you know it's not the United States, don't you?

A. Yes.

Q. And why is that?

A. Because I would have known that and it would have fallen into my area of responsibility.

Q. Okay. So, is it likely the license would have covered Europe?

A. It could have covered anything ex-U.S.

Q. Which includes Europe?

A. Europe, Canada, Mexico, the Far East.

Q. Okay. And those are the same markets, the Far East and Europe, that Bell said the market potential was quite limited for.

A. Again, I don't know if he was talking about this product's market potential or their ability to

commercialize it or their infrastructure there. Remember, I -- we were doing this as a domestic deal, so I had a very vested self-interest to get this deal done for U.S. only. So, his opining on ex-global issues, you know, was of no real concern for me in this particular discussion, and if we had a chance to come back later and get the global option and it was -- and we assessed the value, that would have been all the better.

Q. Jim Audibert wasn't at this meeting, was he?

A. He was not.

Q. Was he involved in the Niaspan discussions at this point?

A. I had included Jim. I mean, remember, Jim has also got responsibility for strategic direction for the cardiovascular products, you know, worldwide and consistently, and he knew some of the players here. So, we had discussions on it.

Q. Did he participate in any of the meetings from April through June with Kos?

A. I recall he was on one telephone conference, but I don't recall if he -- with Kos, that's the only one I recall.

Q. So, you only recall him participating in one phone call?

A. I recall the conference that we had, the big initial conference with Bell and Dave Heatherman, and Jim and I participated on that together.

Q. When did that take place?

A. And he was also -- ah, I don't recall, but we covered it earlier.

Q. Yeah, I think I can point you to that document. I believe it's CX 543. Just tell me if this is the call you remember Jim participating in.

A. Yes, yes.

Q. Okay. And do you recall him participating in any later conference calls with Kos?

A. I don't believe we had any later conference calls with Kos.

Q. Okay. And do you recall him participating in any face-to-face meetings with Kos?

A. I think in total we had one face-to-face meeting.

Q. And he didn't participate in that?

A. So, no. No.

Q. Okay. If you could turn to CX 558, do you have that in front of you?

A. I do.

Q. Okay. And the date on this document is June 9, 1997. Is that right?

A. Yes.
Q. And you were copied on this document.
A. Yes.
Q. And this is a letter from Martin Driscoll?
A. Yes.
Q. And that's your boss?
A. Yes.
Q. And it's to Richard Zahn, right?
A. Yes.
Q. And that's his boss?
A. Yes.
Q. And the subject is Kos' Niaspan.
A. Yes.
Q. And another individual is copied on this, David Poorvin.
A. Yes.
Q. Who is he?
A. I believe at the time he was the vice president of business development, Karin Gast's boss.
Q. Okay. So, he's the head of all in-licensing for pharmaceuticals at Schering?
A. He is -- I believe so. He's in global marketing, but he's the head of that business development group. At the time, we also had a business development group in the U.S. that was parallel to his

group. I believe we had a parallel group, but he's -- he's the head of global business development.

Q. Okay. Mr. Audibert's not listed on this document, is he?

A. He is not.

Q. The first paragraph says, "As you know, we have held discussions with Kos regarding the potential co-promotion of Niaspan (sustained-release niacin) with Key Pharmaceuticals. We have worked hard to assess the potential market value of Niaspan, understand the needs of Kos, and create a potential deal that would yield optimal revenue for Schering-Plough. After an extensive assessment, I recommend we discontinue these discussions."

So, is this the document where Mr. Driscoll recommended to Mr. Zahn to discontinue discussions with Kos?

A. Yes.

Q. Okay. And as far as you know, did any discussions take place subsequent to this?

A. Not that I know of.

Q. Okay. Paula, if you could pull up the third paragraph, please.

The first line says, "Although certain investment firms have publicly stated that Niaspan is a

$250 million product, we don't necessarily share that view."

Here, Mr. Driscoll is saying that Schering doesn't share the view of certain investment firms that Niaspan is a $250 million product. Is that correct?

A. Yes.

Q. And then it says, "Niacin has been available for many years in the U.S. to lower cholesterol values. The immediate-release niacin products cause flushing in most patients. As a result, patient compliance is greatly impacted. Also, the long-term use of the immediate-release niacin can lead to hepatotoxicity."

Do you see that?

A. Yes.

Q. And this talks about just some of the known side effects relating to niacin drugs. Is that right?

A. The immediate release niacins, yes.

Q. Okay. It goes on to say, "Kos maintains that the intensity of flushing with Niaspan is much less than seen with the immediate-release niacin products. Kos also contends that the incidence of hepatotoxicity with long-term use is greatly diminished with Niaspan."

Now, this is referring to what you talked about before, that Kos had certain claims that you were trying to determine whether or not they were -- they

could be substantiated. Is that right?

A. Right, yes, um-hum.

Q. And Mr. Driscoll goes on to say, "Unfortunately, Kos has been unwilling to share the clinical data that would substantiate these claims even though we have a confidentiality agreement in place between the two parties and we have repeatedly asked for this information."

So, according to Mr. Driscoll here, Schering can't substantiate these claims.

A. That's correct.

Q. And "these claims" refers to claims regarding hepatotoxicity and intensity of flushing. Is that right?

A. Right, they characterized that they had reduced side effects in those two issues, and basically when we got to negotiating broad deal terms, their ease in which they provided us with data discontinued, because I -- frankly, they felt that we weren't progressing in our deal terms, and so they no longer were cooperative in providing us with information, which happens a lot in business development deals. I mean, if you're not going to -- if you're no longer going to discuss this, they're likely not to communicate information, whether you have a confidentiality arrangement or not. It

can -- it can often -- if you know some of their data and you're in the middle of negotiations, it can strengthen your position in those negotiations and possibly give you more leverage with the deal. So, it's not unusual during the course of negotiations that they may slowly give you some information until they have a sense as to how serious you are vis-a-vis their deal terms. So, that's not unusual.

Q. So, you didn't get enough information to substantiate their claims.

A. I mean, Marty didn't. I mean, I was beginning to get comfortable with this drug.

Q. Okay, but Marty's your boss, again?

A. Yes, yes.

Q. And this is Marty's view as of June 9, 1997, that he can't substantiate Kos' claims as to their sustained release niacin product for flushing and liver toxicity.

A. Right, that's correct.

Q. If you could turn to the next page of the document, and Paula, if you could pull up the first paragraph.

Okay, this paragraph starts, "An important factor that will impact the acceptance of Niaspan in the marketplace are the current market dynamics of the

'statin' category. As you know, Warner-Lambert's Lipitor (atorvastatin), supported by the co-promotional efforts of Pfizer, is off to a torrid start. Prior to the introduction of Lipitor, Niaspan's opportunity may have resided as an adjunctive therapy with the statin products. It appears that the 'potency of Lipitor' combined with its seemingly benign side-effect profile greatly reduces the need for a product such as Niaspan."

So, here Mr. Driscoll is saying that the market opportunity for a drug like Niaspan -- I'm sorry, that because of the statins, the need for a product such as Niaspan is reduced. Is that right?

A. That's his statement, yes.

Q. And again, he's your boss.

A. Right. I don't necessarily agree with that, but that's happened before.

Q. Okay. It goes on to say, "Niaspan could be relegated to the severe hypercholesterolemic patient who needs a multiple drug regimen. As a result, Niaspan's market opportunity is narrowing even prior to its introduction. Indeed, the use of other classes of cholesterol-lowering products such as niacin, gemfibrozil and cholestyramine has declined since the introduction of Lipitor."

So, here, Mr. Driscoll, your boss, is indicating that the market opportunity for a drug like Niaspan, a sustained release niacin drug, is narrowing even prior to its introduction.

A. That's correct. He misread this market.

Q. He misread this market?

A. I think he did. I absolutely do. I mean, if you look at -- back in time, that was a -- whatever, $5 to $6 billion marketplace. What Lipitor did was it expanded the entire market, almost doubling it. So, what's now happening is multiple meds are applied to this therapy area, and frankly, an outstanding niacin would have been a perfect product.

Additionally, we found out more about HDL over that course of time, and it became a significant contributor to the management of hypercholesterolemia, like we thought it might be. So, everyone was afraid of what Lipitor might do. It had just been launched. We didn't know -- we didn't know the type of investment. So, I think in Marty's mind, he didn't want to have to take the risk that there were factors that might challenge it. In my mind, I thought this would be a very nice, significant product for us and bridge us to our next product.

Q. Okay, but once again, I know I've said this a

few times, Mr. Driscoll is your boss.

A. Right, but again -- go ahead.

Q. And Mr. Driscoll recommended to his boss, Mr. Zahn, to discontinue discussions with Kos on Niaspan.

A. That's correct.

Q. And Mr. Zahn accepted Mr. Driscoll's opinion.

A. That's correct.

Q. And discontinued discussions.

A. That's right.

Q. So, this ended the discussions on Niaspan.

A. It did.

Q. And this memo is dated June 9th, 1997.

A. Yes.

Q. And that was just three days before Mr. Audibert began his evaluation of Niacor-SR?

A. I don't know that.

MR. SILBER: That's all I have, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. SILBER: Actually, I spoke too soon, if I could have a moment, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MR. SILBER: Thank you.

(Counsel conferring.)

MR. SILBER: That's all I have, Your Honor.

JUDGE CHAPPELL: Redirect, Ms. Shores?

MS. SHORES: Yes, Your Honor.

JUDGE CHAPPELL: Take your time, get those binders organized before we start.

MS. SHORES: I am a fluid machine, Your Honor.

REDIRECT EXAMINATION

BY MS. SHORES:

Q. Mr. Russo, do you recall Mr. Silber asking you about price constraints?

A. Yes.

Q. And I think you said that Schering likely raised prices in 1996. Is that right?

A. Yes.

Q. '97 and 1998?

A. Yes.

Q. How much did Schering raise prices of K-Dur by in that time frame, do you know?

A. I don't exactly recall, but it was likely in the 3 to 5 percent range.

Q. Would you characterize that as a large increase or a small increase?

A. No, that was standard. That was the rate of inflation basically.

Q. And did the existence of all of these other competitors to K-Dur constrain how much you could raise your price during that time frame?

A. I think so. I mean, it -- if we were truly a unique product, I would have tried to -- or had new data, new clinical data, I would have been more aggressive in raising the price.

Q. Do you know whether the prices of your competitors' products also went up during that time frame?

A. They likely did.

Q. Okay, I'm not that fluid. Hang on just a sec.

Now, Mr. Silber showed you some testimony from Mr. Driscoll. Do you recall that?

A. Yes.

Q. And he showed you a portion of Mr. Driscoll's testimony, and he suggested that it said that -- or this might have been your prior testimony -- at any rate, that you were more bullish than Mr. Driscoll on the prospects for Niaspan. Do you recall that?

A. Yes.

Q. And he also showed you some testimony of Mr. Driscoll that Mr. Silber suggested meant that Mr. Driscoll thought that Niaspan had a maximum $60 to $70 million potential. Do you recall that?

A. Yes.

Q. I'd like to show you CX 558. That should be in both binders.

A. CX 558?
Q. 558.
A. Yes.
Q. That's the memorandum that Mr. Silber was asking you about from Mr. Driscoll to Mr. Zahn. Is that right?
A. That's correct.
Q. It says here in the second paragraph, "We estimate peak year sales for Niaspan will be $134 million in the year 2002."
Do you see that?
A. Yes.
Q. How does that number, $134 million in the year 2002, compare to your sales projections for Niaspan?
A. Very close.
Q. And if you would just go back to CX 550 in your binder, do you have that? Just one second, I'll bring it up on this screen. Hang on a second.
A. I do.
Q. Would you go back to 550?
A. I think that was it.
Q. And do you see there, sir, under Price Scenario II, do you see that line?
A. Yes.
Q. It's hard to read. If you could look and

see -- in fact, it might be helpful if you could just read, and you can use either the exhibit in your binder or the one on the screen, what the sales figures are for each year up to 2002.

A. I'll give it my best shot. Approximately $7 million, approximately $48 million, approximately $102 million, approximately $107 million, approximately $130 million, and approximately $134 million, and that's through 2002.

Q. And I think actually earlier when I was asking you questions, you might have misread the figure under 2000. I believe that might say $106,941,000. Is that correct?

A. Yes, yes.

Q. So, going back here to CX 554, Mr. Driscoll's memo to Mr. Zahn, how does his projection for the year 2002 compare to your projection?

A. He basically used my base case forecast for year 2002.

Q. Now, again, in this -- in CX 558, which is the memo from Mr. Driscoll to Mr. Zahn, it says, "Under the assumption that we could negotiate terms as favorable as a 50/50 split on gross profits, our revenue would only equal $67 million in the peak year and the 10 year NPV is projected at $127 million."

Do you see that?

A. I do.

Q. First of all, do you have an understanding as to how he arrived at the figure of $67 million?

A. I believe it's simply one-half of the 134.

Q. So, that would be Schering's share of the profits?

A. Of the revenue.

Q. Of the revenue, thank you.

And how does the ten-year NPV in Mr. Driscoll's memo compare with your NPV, net present value figures, in your projections, do you recall?

A. Yeah, it's actually slightly higher.

Q. I'd like you to turn to -- and this is in the binder that Mr. Silber gave you, CX 546. Do you have that, sir?

A. I do.

Q. And again, what is CX 546?

A. This is a description of the Niaspan opportunity, a memo written to myself, copied to members of the team that was looking -- that were looking at this product.

Q. I'll just put it on the ELMO.

Mr. Silber asked you some questions about these items next to what's called due diligence validation.

Do you recall that?

A. I do.

Q. And the issues listed there are patent status, finalized labeling, manufacturing capabilities and product liability. Do you see that?

A. Yes.

Q. And then Mr. Silber read you the following sentence at the end of that page that says, "We would of course subject any deal to that criteria."

Do you recall him asking you that?

A. I do.

Q. Mr. Russo, you wrote this document, did you not?

A. I did.

Q. By "any deal" there, did you mean any deal at Schering or for any product is subject to these criteria?

A. Yeah, that would -- that's a broad interpretation of that. I was just -- I would say no.

Q. Is it likely that you meant, sir, that Schering would, of course, subject any deal involving Niaspan to this criteria?

A. That was likely what I meant.

Q. And finally, if you could turn to CX 576, do you have that, sir?

A. I do.

Q. That's the -- again the Decker Research study?

A. Yes.

Q. Third-party market research.

If you could turn to page 4 of this document, do you see that, sir?

A. I do.

Q. It says there that, "Although the single study did not sell them on Niaspan, lipid experts indicated that they would welcome an effective, safe, FDA-approved sustained-release niacin."

Do you see that?

A. I do.

Q. Was that your recollection of what these lipid experts said about a sustained release niacin product?

A. It was. If they found a good niacin, they would use a lot of it.

MS. SHORES: Thank you. I have nothing further, Your Honor.

JUDGE CHAPPELL: Any recross?

MR. SILBER: Yes, Your Honor.

RECROSS EXAMINATION

BY MR. SILBER:

Q. If you could just stay at that page, please.

The language Ms. Shores just read to you from

paragraph 8 in CX 576 says that lipid experts indicated that they would welcome a safe -- an effective, safe, FDA-approved sustained release niacin, right?

A. Yes.

Q. Did these lipid experts conclude that Niaspan was a safe product?

A. I don't recall. It's -- it seemed like they were liking it. It said they liked the dosing, the efficacy and the safety is essentially equal to immediate release niacin, less flushing than immediate release niacin, and the fact that the patients would receive a consistent product from prescription to prescription. So, it sounds like to me, you know, if they saw final labeling and were able to see clinical data that was included in the NDA, they were going to be supportive of Niaspan.

Q. Okay. But here it's just talking generally about they would welcome this drug if it was effective, if it was safe, if it was FDA approved.

A. Yes.

Q. We all would welcome a drug that's safe, effective and FDA approved, wouldn't we?

A. Yes.

Q. Now, let's go back to page 10 of this document, which is SP 020717, and at the bottom -- let me just

put this up on the ELMO.

This is a paragraph I had shown you before, and in it, here we're talking about Niaspan, we're not just talking about some hypothetical safe, effective, FDA-approved drug, right?

A. It looks that way, yes, uh-huh.

Q. Okay. And they say that they remain unconvinced on the issues of liver toxicity, especially in combination with a statin, and side effects, and those are safety issues, aren't they?

A. Yes.

Q. So, they remain unconvinced on the safety issues for this specific drug.

A. Based on the one study we showed them.

Q. Okay.

That's all I have, Your Honor.

JUDGE CHAPPELL: Anything further?

MS. SHORES: Nothing further, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Russo. You're excused.

THE WITNESS: You're welcome.

JUDGE CHAPPELL: Who's your next witness, Mr. Nields?

MR. NIELDS: Your Honor, the next witness is Mr. Hoffman. Mr. Orlans will be cross examining him.

Mr. Orlans is not available tomorrow, and we had sort of agreed that we would request -- suggest to the Court that it would be good either to do him all today or do him all Friday, direct and cross.

JUDGE CHAPPELL: What's your estimated time for direct?

MR. ORLANS: I think about 20 minutes.

JUDGE CHAPPELL: Estimated cross?

MR. ORLANS: About a half hour, Your Honor.

JUDGE CHAPPELL: What's your plan B if we put him off until --

MR. NIELDS: Call him on Friday, Your Honor.

MR. ORLANS: I think, Your Honor, I'm agnostic on that point. We could do either. I don't know how Mr. Nields feels about it, but either is fine with me.

MR. CURRAN: Your Honor, I have a slight preference that it go today, because we've got a witness on Friday who is available only on Friday, and he might take the full morning until 2:30.

JUDGE CHAPPELL: Right, we're breaking Friday no later than 2:45 for another hearing I have to attend to. Let's press on, but I would encourage the attorneys in the case to make sure that I'm not the last one to find out these scheduling concerns. It would have been better to let me know earlier in the

day or as soon as this became knowledgeable to everyone, but let's go ahead. Let's proceed.

MR. NIELDS: Thank you. I apologize for that, Your Honor. I had actually anticipated Mr. Russo would be done a little bit earlier and it wouldn't be an issue, but we will go ahead.

JUDGE CHAPPELL: Okay.

MR. CURRAN: Thank you, Your Honor.

MS. SHORES: Your Honor, I have one minor housekeeping matter that we might take advantage of this delay to take care of.

JUDGE CHAPPELL: Okay.

MS. SHORES: The parties have a joint stipulation regarding the admission of exhibits into evidence. All the parties have agreed, and I have a copy of the stipulation here, which is marked JX-4.

JUDGE CHAPPELL: And you are going to give the original or an original of that to the court reporter?

MS. SHORES: I am, sir.

JUDGE CHAPPELL: And let me have a copy.

MS. SHORES: I will. May I approach?

JUDGE CHAPPELL: Yes. Joint -- well, before I go any further, you have agreed to this, Ms. Bokat?

MS. BOKAT: Yes, we have.

JUDGE CHAPPELL: And Mr. Curran?

MR. CURRAN: I believe that's my signature on there, Your Honor. Yes, I have.

JUDGE CHAPPELL: JX-4 is admitted, and that includes the exhibits which are listed thereon.

MS. SHORES: Thank you, Your Honor.

(Joint Exhibit Number 4 was admitted into evidence.)

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

JOHN F. HOFFMAN

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name for the record, please.

THE WITNESS: John Fletcher Hoffman.

JUDGE CHAPPELL: This is the other Hoffman.

MR. NIELDS: This is the other Hoffman back for a repeat appearance, Your Honor.

JUDGE CHAPPELL: Okay.

MR. NIELDS: And once again, this time he will be testifying about the Upsher-Smith negotiations, and once again, in conformity with the Court's ruling, I will be asking him about conversations that he had with Upsher-Smith people. Those conversations have been fully explored in deposition by complaint counsel. I

will not be asking him about conversations with his client or mental impressions about the case, which are privileged.

JUDGE CHAPPELL: Okay. You may proceed.

DIRECT EXAMINATION

BY MR. NIELDS:

Q. I'm only going to ask you one repeat question, Mr. Hoffman. How are you employed?

A. I am staff vice president and associate general counsel for Schering-Plough.

Q. And you've already testified that you were in charge of litigation at Schering since sometime in 1996. Is that correct?

A. Early 1996, yes.

Q. And at least throughout 1997, by the time of 1997, you were in charge of patent litigation.

A. That's correct.

Q. Now, did Schering have a patent infringement lawsuit against -- or did Key Pharmaceuticals have a patent infringement lawsuit pending in 1997 against Upsher-Smith?

A. Yes, it did.

Q. Did there come a time when you were involved in settlement discussions with people from Upsher-Smith regarding that case?

A. Yes, there did.
Q. And when was that to the best of your memory?
A. I believe it was in early June of 1997.
Q. And what discussions were you involved in?
A. I had a telephone conversation with a Mr. Nick Cannella, who was outside counsel to Upsher-Smith. I had a meeting in the law department conference room with people from Key, Schering and people from Upsher-Smith.
Q. When you say the "law department conference room" --
A. Yes.
Q. -- you're talking about where?
A. At Schering-Plough in Kenilworth, New Jersey.
Q. And this is a distinct event from your phone conversation with Mr. Cannella?
A. The phone conversation was in preparation for the meeting, but yes, different days. I attended a meeting in Minnesota at Upsher-Smith's headquarters with people from Schering and people from Upsher-Smith. It's outside Minneapolis, I don't know the name of the suburb. And then I had some follow-up telephone conversations or a conversation or conversations from that.
Q. And I think you may have already said this, but

approximately when was your conversation with Mr. Cannella?

A. I don't remember dates particularly, but if we -- I can place it from the settlement agreement, which --

Q. All right, if the settlement agreement is dated the 17th of June --

A. Right, I would put it somewhere around the 10th or a little before of June.

Q. And again, who was -- who was Mr. Cannella?

A. As I understood it, he was outside counsel to Upsher-Smith from the firm that was involved in the patent litigation but antitrust knowledgeable.

Q. And at whose instance did this conversation occur?

A. I asked to have the conversation. I don't know whether I called him or he called me, but I had asked to have the conversation.

Q. What was the subject of the conversation?

A. It was shortly before the meeting that took place in Kenilworth, and the subject was preparing for it. The particular things we discussed were possible settlement of the lawsuit, some antitrust concerns I had, and potential for business dealings between the parties or licensing particularly.

Q. And what was said on those subjects?

A. As I recall, I -- there was a brief introduction, and then I said that -- to Mr. Cannella that I had some antitrust concerns concerning the meeting, that Schering was not going to be paying Upsher-Smith to stay off the market and that I didn't want that subject to be discussed at the meeting, and I know we discussed the type of settlement we were talking about, which was giving them -- giving Upsher-Smith a license to come on the market sometime before the patent term expired, and I think we discussed the date, and then that the meeting was to be really about licensing, and at the end it was a "we'll see you there" kind of discussion.

Q. So, that's how the conversation ended?

A. Yes.

Q. And do you remember when the meeting in Kenilworth took place?

A. Again, backing up from the settlement agreement, I would say somewhere around the 12th or 13th, that would be of June 1997.

Q. And who was there?

A. From the Schering side of the table, we had me, Mr. Kapur, Mr. Ray Kapur, Mr. Jeff Wasserstein, and on the Upsher side of the table, we had Ian Troup, his --

there was a consultant that was with him whose name continually escapes me, and Mr. Cannella.

Q. And who is Mr. Troup?

A. I understood him to be the head of Upsher-Smith. I think his title was president, but I understood him to be the head of the business operation.

Q. And who is Mr. Kapur?

A. Mr. Kapur is in charge of the worldwide generics operation at Schering-Plough and president of the U.S. generic subsidiary.

Q. And who is Mr. Wasserstein?

A. At that point, he was in charge of the corporate business development function, which included licensing.

Q. About how long did the meeting last?

A. I would say somewhere between an hour and two hours, maybe around an hour and a half. It wasn't -- it wasn't a half a day or a day meeting.

Q. And what subject or subjects were discussed at the meeting?

A. A discussion of the settlement of the lawsuit broadly and a discussion of potential licensing of products from Upsher-Smith to Schering.

Q. And which of those two topics, settlement and

licensing, took up more time?

A. Oh, clearly the licensing part of it.

Q. What was said on the subject of settlement?

A. I remember at the beginning of the meeting, there was some brief posturing between Mr. Troup and myself on the merits of the lawsuit, but pretty quickly -- and it wasn't more than a minute or two -- I said, We're beyond that. We've got how we're going to settle this lawsuit. Let's get on to the licensing discussions.

Q. When you say you got how you were going to settle the lawsuit, was there a mention of a date?

A. I believe that the date of September 1, 2001 was mentioned. It was the only date under discussion at that time, but I don't have a very precise recollection of that.

Q. And did he make a response when you said that?

A. Yeah, I think -- I remember the phrase he used was, "That's all well and good for you, John," kind of spreading his arms to mean kind of I took it Schering-Plough, "but I have cash needs, I have all of my company's cash tied up in two products in development," the Klor Con -- the K-Dur generic and what turned out to be the Niaspan product or the sustained release niacin, and I said, Well, I said that

we're willing to do arm's length business deals that stand on their own two feet, and that's what we're here to discuss.

Q. Did anything else come up during the meeting on the subject of settlement?

A. At some point during the meeting, and it was early on, Mr. Troup's consultant or Upsher-Smith's consultant started talking about how much Schering had to lose in the litigation if we lost it. I took that to be an invitation to pay them to stay off the market, and I said we weren't going to do that and I didn't want to discuss that. Mr. Cannella agreed with me, and we moved on.

Q. Now, what was said on the subject of licenses at that meeting?

A. Quite a bit, but the particular subject that was most prominent was the sustained release niacin product. I remember Mr. Troup making a brief presentation on the size of the market for that product and on the product itself. I recall we -- somebody on our side of the table said that we were already familiar with the product through our prior discussions with Kos Pharmaceuticals.

I remember that they had brought a package of materials, I don't know whether it was a half an inch

or an inch thick, that was in a folder, and that was given to Mr. Kapur. I understood it to be some sort of clinical data or data on the product.

I recall Mr. Troup expressing the view that he wanted $70 to $80 million for the rights outside the U.S. for this product, and I remember Mr. Kapur asking whether or not the U.S. rights were available, and Mr. Troup saying no, that Upsher-Smith was keeping those for themselves.

Then I recall there were some other products discussed. I -- there were some that Mr. Troup talked about that Mr. Kapur was not interested in and just said no, we're not interested in that. There were at least two others at that meeting that were discussed, the cholestyramine product, I think it's called Prevalite, and the generic pentoxifylline, and Mr. Kapur was interested in those, although Mr. Troup didn't agree that they were -- to use the vernacular -- "in the deal" at that meeting. He was not being committed on that.

Q. And how was the -- how was it left at the end of this meeting?

A. I don't think we had an agreement on the settlement, but we would get back to them once we had reviewed the clinical data.

Q. Once you'd reviewed the?

A. Clinical data, the data that they had given us at the meeting.

Q. This sort of half inch thick --

A. Half inch or an inch, I don't recall particularly. I remember it being passed across. I don't remember exactly -- I didn't look at it particularly.

Q. And this was data on Niacor?

A. If that's -- yeah, the sustained release niacin product.

Q. Now, did you then have a meeting, a follow-up meeting later?

A. Yes, we did. It was in Upsher-Smith's headquarters in -- outside Minneapolis. I recall we took an extraordinarily early flight and got there very early, but we met in a conference room there. I recall Mr. Troup was there, I believe the gentleman who was a consultant was there. I remember meeting somebody else from Upsher-Smith in the hall, I think it was the CFO, but he didn't play any particular part in the meeting.

Q. Who was there from Schering's side?

A. Aside from me, Mr. Wasserstein, Mr. Kapur and Paul Thompson, who was an attorney in the law department licensing group.

Q. And how -- if you can recall, approximately how many days after the meeting at Kenilworth was the trip to Minnesota?

A. Less than a week, somewhere in there.

Q. What subjects were discussed at this meeting in Minnesota?

A. Again, the settlement of the lawsuit, but mainly licensing.

Q. And what was said on the subject of settlement?

A. Again, Mr. Troup and I went through a little debate for about a minute about the merits of the lawsuit, and then again, it was let's move on to talk about the licensing prospects.

Q. And what was said on the subject of licensing?

A. Again, this meeting lasted somewhat longer, but there was a discussion of the Niacor product. Again, I recall the numbers $70 to $80 million, in that range, from Mr. Troup. I recall -- it wasn't just for Niaspan, but I'll come back to that in a minute -- an offer from our part of $60 million in what I'll call traunches or bites, three bites over two years, and then some milestones, $10 million worth of milestones, ten $1 million milestones on introduction in various major European markets. The scope of the license, which was outside the U.S., I think it's outside the

NAFTA countries, was discussed.

A good part of the meeting was taken up with Mr. Kapur arguing to get the additional products into the deal, if you will, and eventually he did succeed, and pentoxifylline outside the U.S., cholestyramine for U.S. and overseas but not exclusive in the U.S., and the Klor Con product outside the U.S. were put into the deal. That's pretty much it.

Q. How was -- where did things stand at the end of the meeting?

A. I thought we had a deal, but we had to write it up, and we went back to write it up.

Q. And were all the details of the deal agreed to or just the general terms?

A. I think the principal terms were agreed to. I don't know that all of the details that we would do were agreed to, but certainly the principal terms.

Q. And again, in terms of just the settlement, the entry date, what was -- what was agreed to at that time on the entry date?

A. A royalty-free license to Upsher-Smith to come on the market on September 1, 2001, about five years before the product patent expired.

Q. Now, what happened at the -- after the end of the meeting?

A. We flew back to Newark, came into Kenilworth. I know that Mr. Thompson was working on the plane on a draft of the settlement agreement. I recall having a couple of telephone conversations with Mr. Cannella that I wouldn't characterize as substantive, more in the nature of "where is your draft" kind of conversations, that day or the next.

I know we produced a draft and we sent it over to Upsher-Smith or to Mr. Cannella. I remember having a telephone conversation about some terms, I don't remember the particular terms, with Mr. Cannella where I took his comments and passed them along to Paul and to Mr. Kapur, Mr. Wasserstein. And we worked through that next day.

I recall having a telephone conversation with Mr. Troup to find out whether his fax would be -- he would be available by fax to sign up an agreement early in the morning of the following -- not the day following the meeting in Minnesota but the day after that, and he said yes. And somewhere around 3:00 in the morning, we signed up the preliminary or the letter agreement, and I went home, much relieved.

Q. Now, Mr. Hoffman, I think I have included in a binder in front of you at tab 347 a copy of the agreement. Would you look at that and tell me if

that's a copy of the agreement that was reached at 3:00 in the morning?

A. I believe that's it, yes, sir.

Q. Did I say that this was CX 347?

A. Yes.

Q. Okay.

A. In any event, it is.

Q. Now, it bears the date June 17, 1997. If this was signed at 3:00 in the morning, 3:00 in the morning what day?

A. I believe it was the 18th.

Q. Okay. And then that means that you were working on it on the 17th?

A. Yes.

Q. Or somebody was drafting it?

A. Yes.

Q. And that means, then, what would have been the date of your meeting in Minnesota?

A. The 16th.

Q. When was the trial of the case actually to occur?

A. Very shortly thereafter. I don't remember whether it was the 18th or 19th, but it was very shortly thereafter.

Q. During your meetings with Upsher-Smith people,

did you have any discussions with them regarding the 180-day exclusivity provisions of the law?

A. No, sir.

MR. NIELDS: May I have just a moment, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MR. NIELDS: I have nothing further, Your Honor.

JUDGE CHAPPELL: Do you realize that was exactly 20 minutes?

MR. NIELDS: That is the only time in this entire case I have even been close, Your Honor.

JUDGE CHAPPELL: I think a donkey just flew by the window.

Mr. Orlans, cross examination?

MR. ORLANS: Thank you, Your Honor.

CROSS EXAMINATION

BY MR. ORLANS:

Q. Good afternoon, Mr. Hoffman, actually evening, virtually.

A. Excuse me? Good afternoon.

Q. I said, good afternoon or good evening, whichever is more appropriate.

A. Yes, yes.

Q. Mr. Hoffman, let me take you back to the patent

litigation for a few moments. First of all, there were no antitrust or other counterclaims in the patent litigation with Upsher. Is that correct?

A. I don't recall any.

Q. Okay. And that would also be true of the patent litigation against ESI, am I correct?

A. I frankly don't remember.

Q. Okay. In terms of the Upsher patent litigation, you projected that if the trial had gone forward, Upsher had prevailed, that it would have been about a year before Upsher would have been able to go on the market. Isn't that correct?

A. I projected?

Q. That's correct, sir.

A. I don't believe so, no.

MR. ORLANS: May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. ORLANS:

Q. I'll give you a copy of your investigational hearing so that you can have that.

A. Sure.

Q. Let me ask you, sir, to turn to page 79 -- actually, that's wrong, hang on a second.

Actually, where I am is -- yeah, the bottom of 79 and the top of page 80. I'm going to put that on

the ELMO as well.

A. Yes, sir.

Q. Okay, and didn't you testify at your deposition, sir:

"So, it wasn't as if, even if they had won the trial starting June 18th and going for four weeks or whatever it was going to go, that they'd be on the market the next day. If we appealed it would be about a year -- given federal circuit normal time -- before they would be able to go on the market."

Wasn't that your testimony, sir?

A. I don't think that's complete, but that's what it says where you read, sir.

Q. You never corrected that in any way, did you, sir?

A. I don't believe I had to.

Q. On your direct, you talked about a conversation you had with Mr. Cannella. Do you recall that?

A. That's correct.

Q. And he is an outside attorney for Upsher. Is that right?

A. That's correct.

Q. And that conversation you say was prior to the Kenilworth meeting. Is that right?

A. That's right.

Q. Sir, didn't you testify at your investigational hearing that as of the time that you were given a briefing on the second Minnesota meeting, which was a meeting that you had not attended, that you had had no direct communications with any of the Upsher people about settlement as of that date?

A. Could I have that back, please? I believe you're correct, but I just want to make sure I heard it correctly.

MR. ORLANS: Could the reporter reread it, Your Honor?

JUDGE CHAPPELL: Go ahead, Susanne.

(The record was read as follows:)

"QUESTION: Sir, didn't you testify at your investigational hearing that as of the time that you were given a briefing on the second Minnesota meeting, which was a meeting that you had not attended, that you had had no direct communications with any of the Upsher people about settlement as of that date?"

THE WITNESS: Yes, and I believe that's correct.

BY MR. ORLANS:

Q. Okay. Then at page 31, line 21, you were asked whether there were any subsequent phone calls or meetings between Schering or Key personnel and

Upsher-Smith personnel.

Do you see that?

A. Thirty-one --

Q. And your response in the affirmative. Do you see that testimony, sir?

A. Yes.

Q. Okay. And after that, the question went on:

"QUESTION: Was the next communication a phone call or a meeting?

"ANSWER: There was a subsequent meeting. I'm sure there was a phone call setting it up. Although I don't know any details.

"QUESTION: You don't know any details about the phone call?

"ANSWER: About the phone call."

Then it goes on to discuss the meeting.

Do you see that testimony, sir?

A. Yes.

Q. Did you make any reference to any conversation with Mr. Cannella in that deposition -- in that investigational hearing, sir?

A. No, I later corrected this in my deposition to say that Mr. Cannella --

Q. Sir, that's not what I asked you.

A. All right.

Q. I just asked you is there anything in here.
A. No, there's not, if that's the question.
Q. That was the question.
Now, let's go back to the meeting at Kenilworth. That was the third meeting overall. Is that correct?
A. It was the first one I was at, but yes, I think it was the third meeting.
Q. Right, okay. There had been two previous ones you hadn't attended.
A. I believe that's correct, yes.
Q. And at that meeting you discussed the potential for settlement by giving Upsher a royalty-free license at some point prior to the expiration of the patent. Is that right?
A. In a broad sense, yes.
Q. Okay. And Upsher wanted a payment to settle the lawsuit. Isn't that also correct?
A. I believe that to be correct.
Q. Okay. And in fact, they wanted to be paid to stay off the market. Isn't that right?
MR. CURRAN: Objection, foundation, Your Honor. This witness can testify as to what Upsher representatives said but not what they wanted or what they subjectively thought.

BY MR. ORLANS:

Q. Didn't they tell you --

JUDGE CHAPPELL: Hold on.

MR. ORLANS: Surely.

JUDGE CHAPPELL: Are you going to respond or withdraw the question?

MR. ORLANS: I'll withdraw the question.

JUDGE CHAPPELL: Thank you.

BY MR. ORLANS:

Q. Didn't Upsher indicate to you that they wanted to be paid to stay off the market?

A. I believe to me, in the meeting in Kenilworth, as I described, there was something I took to that effect. I'm not sure anybody used those words, but there was something I took to that effect.

Q. And you say you told them you were not going to pay them to stay off the market. Is that correct?

A. Yes, or we're not going to do that or words like that, yes.

Q. And you didn't explain to Upsher why you wouldn't pay them for that purpose, did you?

A. I don't recall whether I said antitrust concerns in that Kenilworth meeting. I did in my -- I believe in my phone call with Mr. Cannella.

Q. You mentioned that Upsher brought in a

consultant who analyzed what Schering stood to lose if it lost the lawsuit.

A. I believe he began to discuss that in the meeting I was in in Kenilworth, yes. I don't know, "analyze" can cover a lot of things, but I believe --

Q. Did you have -- I'm sorry.

A. -- I believe he did start to discuss that in the meeting in Kenilworth, yes.

Q. Do you recall what the consultant was actually analyzing?

A. No.

MR. CURRAN: Objection, the same foundational objection, Your Honor. This witness can testify to what was said at the meeting but not what was done or thought prior to that.

MR. ORLANS: His recollection is exactly the point, Judge. I'm asking what he remembers about what the consultant did.

MR. CURRAN: I'd accept the question reformulated as Mr. Orlans has characterized it now.

MR. ORLANS: I thought that was the question I was asking.

JUDGE CHAPPELL: Okay, so --

THE WITNESS: Sorry to --

JUDGE CHAPPELL: -- let's restate the question.

MR. ORLANS: Surely.

BY MR. ORLANS:

Q. Do you recall what the consultant was analyzing when he did his analysis?

MR. CURRAN: Objection, foundation.

JUDGE CHAPPELL: I'll sustain it. You can ask him if he knows what he was analyzing.

BY MR. ORLANS:

Q. You saw the consultant doing an analysis. Is that correct, sir?

A. No.

Q. Oh, you didn't?

A. No.

Q. What did you see?

A. He began talking about an analysis. I don't know -- I certainly didn't see him do one there.

Q. Okay. And the analysis that he began talking about was an analysis of how much Schering would lose. Is that correct?

A. That's correct.

Q. Okay. And did he further explain what he meant or what the basis for his analysis was?

A. Not before I stopped him, no.

Q. Mr. Troup told you that Upsher had a need for income and would have to do some sort of a deal so that

they could get income. Isn't that right?

A. I think the word he used was "cash," but yes.

Q. Didn't you tell Mr. Troup in response that Schering would find a way to provide Upsher with income to make up for what they expected to earn from their generic K-Dur had Upsher been able to go on the market with it?

A. I don't believe I said that. I don't remember saying that. I recall saying that I would be comfortable with a business deal that stood on its own two feet.

Q. Wasn't that, sir, Schering's position with respect to the payment?

MR. NIELDS: Objection, because the "that" is unclear.

BY MR. ORLANS:

Q. Okay. Wasn't -- well, strike that, let me do it this way:

Let me ask you, sir, to turn to -- well, actually, it's not a document we've given you, so let me do that.

Your Honor, may I approach?

JUDGE CHAPPELL: Yes.

Mr. Nields, I assume if a question is withdrawn, you are withdrawing your objection as well.

Is that correct?

MR. NIELDS: Yes, Your Honor, I am.

JUDGE CHAPPELL: Okay.

BY MR. ORLANS:

Q. I'm showing you Commission Exhibit CX 338. Is that a document that you've seen before, sir?

A. I believe so, yes.

Q. Okay. And this was the presentation made to Schering's board in connection with the Upsher-Smith license. Is that right?

A. It's the written material that was distributed before the board meeting, yes.

Q. Okay. Let me direct your attention, sir, to page 270, which is I believe the fifth page in. Doesn't that page state as follows, middle of the paining under Payment Terms:

"In the course of our discussions with Upsher-Smith, they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next 24 months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit."

Do you see that, sir?

A. Yes, I see that. That does --

Q. And that was what the board was told about this

deal. Is that right?

A. It's in the board presentation, yes.

Q. After Mr. Troup told you about Upsher's need for money, it was at that point that you began discussing the license of Niacor. Isn't that right?

A. It was at that point in the meeting that the subject of Niacor was discussed, yes.

Q. Okay.

A. After that.

Q. And whether or not other products were discussed for licensing purposes, Niacor was the major licensing opportunity in your mind. Isn't that right?

A. That was certainly my understanding, yes.

Q. Sir, at the time of this meeting in Kenilworth, Schering had not done anything that you would call an evaluation of Niacor for licensing purposes. Is that right?

A. I believe you're correct on Niacor.

Q. In that third meeting, sir, you had a discussion of a range of possible entry dates, but a specific date was not picked in that meeting. Isn't that right?

A. I don't think it was picked. As I said at the beginning, there was some posturing -- I called it chest-thumping I think at one point -- between me and

Mr. Troup on that subject. I only recall September 1, 2001 as the date. There may have been some dates right around that area discussed, but that's all I recall. I -- I will agree that at least my investigational hearing does say differently.

Q. You said that you discussed a range of dates. Is that right?

A. Yes.

Q. And you hadn't settled on one as of the close of that meeting.

A. I think that's correct, yes.

Q. And similarly, with licensing-in of Niacor, you had not agreed on the particular terms, correct?

A. Is that question as of the end of the Kenilworth meeting?

Q. That's correct, sir.

A. Terms had been discussed, but no, we had no agreement on it.

Q. Do you know whether prior to the patent litigation anyone at Schering had ever talked to Upsher about licensing Niacor?

A. I don't know.

Q. Let me move on to the fourth meeting, which was the one in Minneapolis, actually your second meeting, if that's a better way to describe it.

A. I don't want this to be misleading. You keep mentioning third and fourth meetings. I think there may have been one more.

Q. Okay, why don't we talk in terms of the meetings you attended --

A. Why don't we talk about the one in Minnesota. Would that be more comfortable?

Q. That's fine. So, of the meetings you attended, you attended one in Kenilworth, which we have been discussing, and you attended a second meeting in Minnesota.

A. Yes.

Q. And the second meeting in Minnesota that you attended was the final meeting, essentially the one where the final terms were reached. Is that right?

A. Subject to having them written up and signed, yes.

Q. And at that meeting, you discussed the settlement of the lawsuit and the date of September 1, 2001 as the entry or license date. Is that correct?

A. That's correct.

Q. And you also discussed the licensing of Niacor and several other products. Is that correct?

A. Right.

Q. And also the money that Schering would pay,

correct?

A. For the licenses, yes.

Q. Well, actually, sir, you say for the licenses, but in fact, doesn't the agreement indicate that the money is to be paid for all of the rights acquired by Schering, including the settlement of the patent lawsuit?

A. That's what the I think paragraph 11 seems to say. It was directly contrary to every discussion we had had, but --

Q. Well, sir, let's talk about that agreement for a minute, and maybe I will provide you with a copy. Actually, I think it's in the booklet that you have in front of you, CX 347.

A. Yes, sir.

Q. I assume this agreement was written up by people who are careful in writing agreements. Would that be fair to say?

A. I believe Mr. Thompson to be a careful lawyer, yes.

Q. If you look at paragraph 11, sir, isn't it explicit -- oh, I should do that, thank you. We're looking at paragraph 11, which is --

A. Of the attachment?

Q. Yes, of the attachment, which is 194 is the

last Bates number.

And doesn't that paragraph 11 explicitly state, "In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, SP Licensee," that is Schering-Plough, "shall make the following payments to Upsher-Smith," and then it lists the payments. Is that correct?

A. That's what it says, yes.

Q. And the paragraphs referred to for which consideration is being paid include paragraphs that explicitly talk about settlement of the lawsuit and the entry date, do they not?

A. That's correct.

Q. Okay. So, on the face of this agreement, it's explicit and clear, is it not, that the money to be paid was paid at least in part for the settlement of the lawsuit?

A. You could interpret it that way.

Q. Sir, isn't that explicit?

A. I don't want to quibble with you.

MR. NIELDS: Your Honor, I object. I just think that's a complete mischaracterization.

MR. ORLANS: I'm just asking him whether that's not what the face of the agreement says, Judge. I don't think this is a question of interpretation.

BY MR. ORLANS:

Q. This is a question of simply reading the language, sir. Isn't that what the language says?

A. Well, sir, if you read the language, you would realize that this also includes the milestone payments, which clearly weren't payment for any entry, but I don't want to quibble with you. I agree with your general remark.

Q. Okay. At this meeting --

JUDGE CHAPPELL: Just so I'm clear, the witness answered before I could rule on your objection, Mr. Nields, so --

THE WITNESS: I apologize.

JUDGE CHAPPELL: -- I believe in his response to his objection that Mr. Orlans clarified the issue and the witness responded, so with that, I will have to effectively overrule the objection.

MR. ORLANS: Or decide its moot, one of the two.

BY MR. ORLANS:

Q. At this meeting, Mr. Troup started out wanting $70 to $80 million. Is that correct?

A. Yes, that's what I said.

Q. And you negotiated down to $60 million?

A. In three bites over two years, plus some

milestones.

Q. And didn't Mr. Troup tell you that he needed a revenue stream to replace what they were not going to get?

A. He -- he may have said that, yeah. I recall him specifically talking about the need for cash, but I think that sounds familiar.

Q. Okay. And the $60 million in bites that you settled on as a payment, those payments were up front and nonrefundable. Isn't that correct?

A. They were nonrefundable. They were over two years.

Q. Okay.

A. I don't know if that's up front or not, but that's what they were.

Q. Okay, I stand corrected. They were nonrefundable and they were noncontingent.

A. That's correct.

Q. In terms of --

MR. NIELDS: Wait a minute, I don't --

THE WITNESS: I don't think that's correct, actually.

BY MR. ORLANS:

Q. Oh, you don't think that's correct?

A. No, I don't believe that's correct.

Q. What was the -- what were those payments contingent on, sir?

A. I'll have to take a look at the agreement, if you will just give me a second.

Q. Okay.

A. Paragraph 12, if the licenses were declared invalid that we got from Upsher-Smith by anybody, we didn't have to make the payments.

Q. Okay, but so long as the licenses were not declared invalid, the money had to be paid, correct?

A. I guess as you would suspect, yes.

Q. And in fact, the money was paid, wasn't it?

A. Yes, it was.

Q. None of the milestone or other payments were ever made, were they?

A. I don't believe so.

Q. Let me go back for a few minutes and discuss Niacor, and again, in your view, Niacor was the major licensing opportunity and not the other products. Is that correct?

A. That's the way I understood it.

Q. And in fact, that's what the board was told as well. Isn't that right?

A. Probably.

Q. Niacor was not FDA approved at that time, was

it?

A. I don't believe so, no.

Q. And in fact, it never received approval, did it?

A. Not that I know of.

Q. Isn't FDA approval important for a number of reasons, including demonstrating that the product's a viable commercial product?

A. These were ex-U.S. licenses.

Q. Correct.

A. I suppose it would be nice to have FDA approval, but it probably doesn't matter that much.

Q. But it would have been a significant factor in assuring the company that the drug was a viable drug, wouldn't it?

A. I don't know what would assure the company that it was a viable drug, sir.

Q. Is it something that --

A. I did not do --

Q. I'm sorry?

A. I did not do an evaluation of this product.

Q. Okay. In negotiations with Upsher, did you ever consider making the $60 million contingent on FDA approval?

A. I don't recall that being discussed.

Q. You have done that with other products, have you not?

A. It may surprise you to know I don't negotiate licenses generally. I don't know, but I -- you're probably right, but I don't know.

Q. Well, sir, last week we discussed ESI and its license, did we not, and we talked about how in the context of the ESI agreement and what you called a bet, you essentially bet on FDA approval. Do you remember that?

A. Yeah. That seems like apples and oranges to me, but yes, I recall that.

Q. Okay. Was there any discussion of including a provision in the agreement in the event that Niacor was not FDA approved?

A. As I said, not that I recall.

Q. How about discussions about including a provision in the agreement that would have required the parties to use best efforts to carry out their respective obligations, did you discuss such a provision?

A. I don't recall.

Q. How about a provision that would have required Upsher to provide reports to Schering on Upsher's continuing developmental efforts on Niacor?

A. I don't recall a particular discussion about that. This was the material terms of the agreement, not all the terms.

Q. Was there any discussion of creating a committee comprised of representatives of companies to oversee implementation of the agreement?

A. Not that I recall.

MR. ORLANS: I have no further questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. NIELDS: I have a few redirect, Your Honor.

REDIRECT EXAMINATION

BY MR. NIELDS:

Q. Mr. Hoffman, during any of your discussions, did Schering ever agree to pay Upsher-Smith for delay?

A. No.

Q. During any of your discussions, did Schering agree to pay Upsher-Smith more than the licenses it received were worth?

A. No.

MR. ORLANS: Objection, Your Honor. I don't think this gentleman is qualified to know what the licenses that were agreed to were worth. He's already testified that he's not an expert in licensing, and he doesn't evaluate licenses.

JUDGE CHAPPELL: Sustained.

BY MR. NIELDS:

Q. Mr. Hoffman, during any of the discussions that you had with Upsher-Smith, did anyone from Schering's side tell Upsher that they would pay them any more than the licenses they received were worth?

A. No.

Q. Now, you were shown the memorandum that went to the board.

A. 338?

Q. CX 338.

A. Yes, sir.

Q. You were shown one page of that document. I'm going to ask you to look at the third page in.

A. Including the cover or not?

Q. Including the cover.

A. Okay.

Q. So that it's got the Bates numbers 1200268 at the bottom.

A. I have it.

Q. And at the bottom of the second paragraph, the very bottom part of it says, "we informed them that any such deal should stand on its own merit, independent of the settlement."

Is that an accurate description of what you

told Upsher-Smith at the meetings you attended?

A. Yes, that's what I meant by "stands on its own two feet."

Q. Now, going to the agreement itself, which is in the binder in front of you, and it's CX 347, you were asked a question by Mr. Orlans about paragraph 11 that has a statement at the beginning, "In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above," and 1 through 10 is basically most of the rest of the agreement --

A. Right.

Q. -- it -- I want to ask you about the rest of paragraph 11. There are little -- I don't know how you call these, but I call them little Roman i and little Roman ii and little Roman iii.

A. Right.

Q. And it mentions a $28 million figure, a $20 million figure, a $12 million figure. Is it true that in each case that is described as a royalty payment?

A. It's an up-front payment royalty payment, yes.

Q. And in your understanding of the word "royalty," is that usually for license rights received?

MR. ORLANS: Objection, Your Honor. He's asking for an expert opinion.

MR. NIELDS: Your Honor, I think Mr. Hoffman

was asked on direct to try to interpret this --

MR. ORLANS: That's absolutely wrong. All I asked him to do was read it, Judge. We had a bit of dispute over this, but all I wanted to know was what the language of the document said. I never asked for interpretation of it.

MR. NIELDS: Well, fine, I'm happy to rephrase.

JUDGE CHAPPELL: Okay.

BY MR. NIELDS:

Q. Is it true, Mr. Hoffman, that in the case of every one of these payments, the agreement describes it as a royalty?

A. Yes.

Q. Now, you were asked at the very beginning of the cross examination about some testimony you gave at the investigational hearing that essentially had you -- I don't want to paraphrase too much -- but essentially had you saying that prior to the meeting in Kenilworth, you had not had a telephone conversation with anyone from Upsher-Smith. Do you remember that?

A. I think that was the thrust of the question, yes.

Q. Now -- and why was it that you said that at your investigational hearing?

A. Because I had --

MR. ORLANS: Wait a minute, I am going to object to this, Your Honor. Why he said something at his investigational hearing is certainly his state of mind, which we are not supposed to be going into given the scope of this witness' testimony.

MR. NIELDS: Well, I'm perfectly happy to reframe it, Your Honor.

BY MR. NIELDS:

Q. Did you --

JUDGE CHAPPELL: Well, he has -- he is going to be allowed to recross him on something you asked on -- or redirect him on something you asked on cross, but let him rephrase it and see if you still object.

MR. ORLANS: Okay, all I asked, Judge, was whether that was what he said at his investigational hearing. I didn't ask for any explanation of why he said anything.

BY MR. NIELDS:

Q. Did you later correct that testimony?

MR. ORLANS: Objection, Your Honor. Prior consistent statements under both the FTC's deposition rules and under clear Supreme Court precedent are not admissible except to the extent that the motive for rendering those prior consistent statements was in between the statement and -- let me rephrase that.

One can use prior consistent statements only when a motive for not telling the truth intervenes and came after the statement. In this instance, whatever motive this gentleman had for telling the truth or not telling the truth had already occurred as of the time of the investigational hearing. The fact that he made a subsequent statement at a deposition is not admissible as a prior consistent statement under those circumstances, under clear Supreme Court law.

Moreover, under our deposition rules, it is inappropriate to refer to a subsequent deposition of a witness who is being called by a party. There's no basis for doing it.

JUDGE CHAPPELL: Do you want to address that or withdraw and reframe the question, Mr. Nields?

MR. NIELDS: I beg your pardon, Your Honor?

JUDGE CHAPPELL: Do you want to respond to that or do you want to withdraw the question?

MR. NIELDS: Well, I think I probably want to respond to it, two ways. One is Mr. Orlans asked Mr. Hoffman himself about another answer, did you correct that at any time, and I'm asking him the same question.

MR. ORLANS: Your Honor, he gave testimony at his investigational hearing. I didn't ask him about that testimony in the deposition. The fact of the

matter is that if that testimony deviated, it's not appropriate for counsel to refer to it. It's a prior -- an effort to try to rehabilitate a witness by using a prior consistent statement, and as I say, the Supreme Court is quite clear on this, that that can be done only in the circumstances where the motive for not telling the truth came after the statement was made.

JUDGE CHAPPELL: Did you ask him on cross if he corrected that statement later?

MR. ORLANS: No, I did not, Your Honor. He tried to volunteer that, and I cut him off.

JUDGE CHAPPELL: Well, I think the authority you're talking about goes to counsel trying to offer the deposition or offer the information. He's merely asking the witness if it was corrected, and I'm going to allow that. The objection's overruled.

THE WITNESS: I think I have the question. Yes, in my investigational hearing, I had mistakenly placed Mr. Cannella at the meeting in Minnesota --

JUDGE CHAPPELL: Mr. Hoffman, the question requires a yes or no answer.

THE WITNESS: Yes, I did correct it.

BY MR. NIELDS:

Q. And when did you correct it?

A. At my deposition.

Q. And what did you say at your deposition?

JUDGE CHAPPELL: We don't need to get into that. I'm not going to allow that.

BY MR. NIELDS:

Q. Okay. At the time of your investigational hearing, did you remember which meeting Mr. Cannella had attended?

A. I remembered incorrectly. I thought Minnesota, but I wasn't sure. It turned out that was incorrect.

MR. NIELDS: I have nothing further, Your Honor.

JUDGE CHAPPELL: Recross?

MR. ORLANS: A few questions, Your Honor.

RECROSS EXAMINATION

BY MR. ORLANS:

Q. Just so that we're clear on this, Mr. Hoffman, Schering did agree to pay Upsher by providing them with a guaranteed income stream for the next 24 months to make up for the income they had projected to earn from the sales of Klor Con had they been successful in their suit. Isn't that right?

A. I wouldn't have characterized it that way, but you correctly read what it says on that piece of paper.

Q. And that's how it was characterized to the board of directors. Isn't that correct?

A. That's correct.

Q. Now, earlier in this document -- could we bring this up on screen, 338, and I want page 3.

MS. KATZ: What's the Bates number?

MR. ORLANS: 268. Could we blow up the second paragraph?

THE WITNESS: Yes, sir.

BY MR. ORLANS:

Q. Okay, during redirect examination, Mr. Nields read a portion of that document, sir, but he took only a portion of that sentence. He didn't read you the full sentence, did he?

A. He read me all of the sentence that's shown there, yes.

Q. Again, sir, he didn't read you the full sentence, because it's not there. Isn't that correct?

A. I believe that's correct.

Q. So, we don't know what the rest of that sentence says, do we?

A. I don't know what --

Q. At least on this record.

A. I don't know what we know, but you can't read it on this document.

Q. At least on this record, we don't know what that statement was. Is that correct?

A. I assume you're correct.

Q. So, for all we know, sir, the first part of that sentence could read, "Although we are in a position where we must pay for delay, we informed them that any such deal should stand on its own merit independent of the settlement." From this record, we can't say whether that's a correct or incorrect statement, right? We just don't know.

A. I believe you do, but from this record, I suppose you don't.

Q. Fair enough.

So, again, just to make the point, what you've done or what Mr. Nields read you was a sentence fragment taken out of context that we don't have the rest of the context, correct?

A. That's one way of looking at it, yes.

MR. ORLANS: I have no further questions, Your Honor.

MR. NIELDS: Nothing further, Your Honor.

JUDGE CHAPPELL: Thanks, Mr. Hoffman. You're excused.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: Who's your next witness, Mr. Nields?

MR. NIELDS: Our next witness isn't here now,

but our next witness is Dr. Horovitz.

JUDGE CHAPPELL: Is he going to be a controversial witness?

MR. NIELDS: I never know what will generate controversy, Your Honor. He will --

JUDGE CHAPPELL: We seem to start off with a lot of controversy in the mornings around here.

MR. NIELDS: I don't think there will -- I don't think there will -- well, I shouldn't say. I don't -- he's an expert witness, Your Honor. Maybe they will make some sort of motion, but I doubt it. He will be on for a reasonable period of the day, I would anticipate.

JUDGE CHAPPELL: Okay, thank you.

We'll adjourn until tomorrow at 9:30.

(Whereupon, at 6:28 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 13, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/14/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE